UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

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GILEAD SCIENCES, INC., GILEAD SCIENCES: IRELAND UC, and GILEAD SCIENCES, LLC,

Case No. 21-cv-4106 (AMD) (RER)

Plaintiffs,

v.

SAFE CHAIN SOLUTIONS, LLC; PATRICK BOYD; CHARLES BOYD; WORLDWIDE PHARMA SALES GROUP, INC. d/b/a PHARMASALES.COM; ADAM S. BROSIUS; BOULEVARD 9229 LLC; ISHBAY SHUKUROV;: PETER KHAIM; ZAFAR ABDULLAEV; PROPHARMA DISTRIBUTION LLC; LEVI ELLIS; SYNERGY GROUP WHOLESALERS LLC; CARLOS VEGA; ISLAND CHEMISTS, INC. d/b/a MEADOW DRUGS & SURGICAL; RANDOLPH MOHABIR; V.L.S. PHARMACY INC.; GOPESH M. PATEL; LIN PHARMACY INC. d/b/a MAKKI PHARMACY; SAMUEL YAKUBOV; MONICA A. NGO; ASCENSION PHARMACY HOLDINGS I LLC d/b/a MERMAID RX AND ARIEL PHARMACY; ALEX GELBINOVICH; PAUL ROSELL; MED-CONNECT ENTERPRISES, LLC; DHRUV RALHAN; D&K HEALTHCARE SOLUTIONS LLC: VENKATA SRINIVAS MANNAVA: DSP CONSULTING INC.; JOHN PANAGIOTOPOULOS; MIKE ZANGARI; RICCARDO MASSANA; STREAMLINE RX LLC; PAVAN MANTRIPRAGADA; MFK MANAGEMENT LLC d/b/a BOULEVARD 9229 & 9229 BOULEVARD; MAKE IT HAPPEN MARKETING INC.; QUAN HERNANDEZ; SCRIPTS WHOLESALE INC.; STEVEN DIAMANTSTEIN; USDV PHARMA LLC; NER250 LLC d/b/a SCRIPTS WHOLESALE; JEFFREY S. BEETLEY; MARYLAND PHARMACIES INC. d/b/a THE MEDICINE SHOPPE #1802; PRIMERX INC.; SEKAR VENKATESH; OMOM PHARMACEUTICALS INC.; OMOM WHOLESALE CORP.; GUSTAVO: FERNANDEZ; LUIS D. GONZALEZ HERRERO; : JORDAN RODRIGUEZ MATO; INVICTA WHOLESALE SUPPLY LLC; JORGE CABA; RXWHOLESALE.COM LLC; GABRIEL BETESH; DANIEL GELBINOVICH; CESAR CASTILLO WHOLESALERS LLC f/k/a CESAR CASTILLO LLC; DNS DISTRIBUTOR LLC; JULIO MARTIN GONZALEZ; PHARMA PAC WHOLESALE CORP.; ANGEL TORAL; GENTEK LLC; EDEL REYES; RAPID'S TEX WHOLE SALES CORP; JOHN SANTOS; TITAN: DISTRIBUTION & SERVICES LLC; TIDY GARAGES L.L.C.; GABRIEL DELGADO RAMIREZ; CM PHARMACEUTICAL LLC; JEFFREY W. GAFNEA; ROBERT W. GAFNEA; : JM SMITH DISTRIBUTION CORP.; CARLOS HERNANDEZ; ASB WHOLESALE DISTRIBUTORS LLC; SILVERLINE PHARMA LOGISTICS LLC; ALBERTO ALONSO DIAZ,

Defendants, and

SWETHA KETINENI; BABASHILOH: ENTERPRISES LLC; 5 CONTINENTAL LLC; AP: FUNDING LLC; 441 WILLIS AVE LLC; LA VIE: JEWELS OF NY LLC; and AG WORLDWIDE: PHARMA SALES, INC.,

Relief Defendants. :

THIRD AMENDED COMPLAINT

Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC (together, "Gilead" or "Plaintiffs"), by and through their counsel, Patterson Belknap Webb & Tyler LLP, for their Third Amended Complaint against the Defendants listed in Appendix A hereto, allege as follows:

SUMMARY OF THE ACTION

1. In this action, Gilead seeks to put an immediate and permanent stop to Defendants' knowing and willful sale, marketing, and distribution of counterfeit prescription drugs. The counterfeits are of Gilead medications, including Gilead HIV medications: life-

saving treatments for patients living with HIV, and pre-exposure prophylactic, or PrEP, medication that protects against HIV-1 infection when taken as prescribed. Defendants sold authentic-looking bottles of Gilead HIV and other medication to distributors and pharmacies throughout the United States, including in New York City, who in turn dispensed them to patients. But, for some of those bottles of purported Gilead HIV medications, the tablets inside those bottles were not Gilead's HIV medication. They were completely different drugs. And all of the purported Gilead HIV medications sold by Defendants were sold with counterfeit documentation that misrepresented the provenance of the medications.

- 2. The counterfeiters used authentic Gilead bottles that at one point contained authentic Gilead HIV or other medications. The tamper-evident seals of these authentic bottles had been broken and their contents emptied. The counterfeiters inserted the foreign tablets into these empty bottles, and then re-sealed the bottles. The counterfeits were thus engineered to resemble a new, unopened, and authentic bottle of authentic Gilead medication. Because federal law requires that all prescription drugs be accompanied by a "pedigree" a document tracking every sale of the bottle from seller to seller, all the way back to the manufacturer Defendants distributed the counterfeits with falsified documentation fraudulently purporting to trace the counterfeits to an authentic source.
- 3. The danger these counterfeits pose is dire. Those who receive and ingest these counterfeits unwittingly miss their HIV treatment or falsely believe themselves to be protected against HIV infection. The foreign drugs in the counterfeit bottles were never prescribed by those individuals' doctors and could cause serious harm or death, through contraindicated drug-drug interactions or the onset of unanticipated side effects such as loss of consciousness while operating heavy machinery or driving. The counterfeit pedigrees with

which these products are sold makes it impossible to verify where the products came from, how they have been handled and stored, and what pills are in the bottles.

- 4. Gilead's investigation has revealed that dozens of individuals and entities were involved in the marketing and sale of counterfeit Gilead-branded medications. These individuals and entities are the Defendants here. As alleged below, Defendants willfully trafficked these dangerous counterfeits and committed fraud to cover it up.
- 5. Gilead's investigation has also revealed that most, if not all, of the counterfeit Gilead-branded medications sold in the U.S. market originate from an organized counterfeiting ring. This counterfeiting ring, led by three individuals (the "Leader Defendants"), utilizes a shifting series of fly-by-night corporate entities ("Supplier Defendants") to supply counterfeits to established gray-market pharmaceutical distributors ("Distributor Defendants"), who then distribute them to pharmacies throughout the United States. The counterfeiting ring has its own dedicated sales force (the "Marketer Defendants") who partner with the Distributor Defendants to aggressively market counterfeits to U.S. pharmacies. Most of the proceeds of the counterfeiting ring are transferred to a series of shell entities (the "Asset Holder Defendants") which use these proceeds to purchase enormous quantities of gold bullion, jewelry, luxury items, and other goods that are difficult to trace and can be easily converted to cash.
- 6. In this action, Gilead seeks injunctive relief, including a seizure at certain Defendants' premises, in order to put an immediate stop to the sale of these dangerous counterfeit medications. Gilead also seeks other injunctive and monetary relief against all Defendants for trademark infringement in violation of Section 32 of the Lanham Act (15 U.S.C. § 1114); false descriptions and false designations of origin in commerce in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125); trademark dilution in violation of Section 43 of the

Lanham Act (15 U.S.C. § 1125) and New York General Business Law § 360-1; deceptive business practices in violation of New York General Business Law § 349; common-law unjust enrichment and unfair competition; engaging in a pattern of racketeering activity in violation of RICO, 18 U.S.C. § 1962(c); and conspiracy to engage in a pattern of racketeering activity in violation of RICO, 18 U.S.C. § 1962(d).

THE PARTIES

7. A list of the parties to this action, and of the Defendant Groups referred to here, is presented in Appendix A hereto, which is hereby incorporated into this Third Amended Complaint as if fully set forth herein.

A. PLAINTIFFS

- 8. Plaintiff Gilead Sciences, Inc. is a public corporation organized under the laws of the State of Delaware, with more than 12,000 employees. Its principal place of business is 333 Lakeside Drive, Foster City, California 94404. Gilead develops and markets a large portfolio of lifesaving medications, including drugs for the treatment or prevention of HIV. Gilead is the owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and package inserts of certain genuine HIV and other medications.
- 9. Plaintiff Gilead Sciences Ireland UC ("Gilead Ireland") is a private unlimited company organized under the laws of Ireland, with its principal place of business at IDA Business & Technology Park, Carrigtwohill, Co. Cork, Ireland. Gilead Sciences, Inc. is the ultimate parent of Gilead Ireland. Gilead Ireland is the owner of certain well-established and famous registered trademarks that appear on the packaging, tablets, and instructional inserts of certain genuine HIV and other medications.
- 10. Plaintiff Gilead Sciences, LLC is a private limited liability company organized under the laws of the State of Delaware, with its principal place of business at 333

Lakeside Drive, Foster City, California 94404. Gilead Sciences, Inc. is the ultimate parent of Gilead Sciences, LLC. Gilead Sciences, LLC is the owner of at least one well-established and famous registered trademark that appears on the packaging, tablets, and instructional inserts of certain genuine HIV and other medications.

11. Gilead Sciences, Inc., Gilead Ireland, and Gilead Sciences, LLC (together, "Gilead") are the collective owners of a number of well-established and famous registered trademarks (the "Gilead Marks") that appear on its genuine medications. A complete list of these trademarks is depicted at Exhibit A hereto. Gilead also owns and uses distinctive packaging (the "Gilead Trade Dress") to distinguish its medications in the marketplace, which is depicted at Exhibit B hereto.

B. ORIGINAL DEFENDANTS

1. Safe Chain Defendants

- 12. Defendant Safe Chain Solutions, LLC ("Safe Chain") is a Delaware limited liability corporation with a principal place of business in Cambridge, Maryland.
- 13. Defendant Patrick Boyd is an individual residing in Maryland. Together with his brother Charles, Patrick Boyd is a founder, owner, and managing principal of Safe Chain. Patrick Boyd managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV and other medications. Patrick Boyd directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.
- 14. Defendant Charles Boyd is an individual residing in Maryland. Together with his brother Patrick, Charles Boyd is a founder, owner, and managing principal of Safe Chain. Charles Boyd serves as CEO of Safe Chain. Charles Boyd managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV and other medications.

Charles Boyd directly financially benefitted from the counterfeiting and had the ability to stop it, but did not do so.

2. Worldwide Pharma Defendants

- 15. Defendant Worldwide Pharma Sales Group, Inc. d/b/a Pharmasales.com ("Worldwide Pharma") is a Delaware corporation with a principal place of business in Delray Beach, Florida.
- 16. Defendant Adam S. Brosius is an individual residing in the United States. Brosius is the founder, owner, and principal of Worldwide Pharma. Brosius managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV and other medications.

3. Boulevard Defendants

- 17. Defendant Boulevard 9229 LLC ("Boulevard") is a New York limited liability corporation with a principal place of business in Rego Park, Queens, New York.
- 18. Defendant Ishbay Shukurov is an individual residing in Brooklyn, New York. Shukurov is the owner of record of Boulevard. Shukurov managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV and other medications.

C. DEFENDANTS NAMED IN FIRST AMENDED COMPLAINT

1. Additional Boulevard Defendants

19. Defendant Peter Khaim is an individual residing in Queens, New York. Khaim is an off-the-books principal of Boulevard. Khaim has sometimes used the last name "Khaimov." Khaim managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications.

20. Defendant Zafar Abdullaev is an individual residing in Queens, New York. Abdullaev is an off-the-books principal of Boulevard. Abdullaev managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications.

2. ProPharma Defendants

- 21. Defendant ProPharma Distribution LLC ("ProPharma") is a Colorado limited-liability corporation with a principal place of business in Colorado.
- 22. Defendant Levi Ellis is an individual residing in Colorado. Ellis is the founder and owner of ProPharma. Ellis managed, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications.

3. Synergy Defendants

- 23. Defendant Synergy Group Wholesalers LLC is a New Jersey limited liability corporation with a principal place of business in New Jersey.
- 24. Defendant Carlos Vega is an individual residing in Florida. Vega is the founder and owner of Synergy. Vega, supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead HIV medications.

4. Pharmacy Defendants

- 25. Defendant Island Chemists, Inc. d/b/a Meadow Drugs & Surgical is a retail pharmacy with a principal place of business in East Meadow, New York.
- 26. Defendant Randolph Mohabir is the principal and supervising pharmacist of Island Chemists, Inc. d/b/a Meadow Drugs & Surgical and is a resident of New York. Among other things, supervising pharmacists are individually responsible for ensuring a pharmacy's compliance with the Drug Supply Chain Security Act ("DSCSA") and other laws and ensuring the authenticity of medications and pedigrees purchased and sold by the pharmacy.

- 27. Defendant V.L.S. Pharmacy Inc. is a retail pharmacy with a principal place of business in Brooklyn, New York.
- 28. Defendant Gopesh M. Patel is the principal and supervising pharmacist of V.L.S. Pharmacy Inc. and a resident of New York. Among other things, supervising pharmacists are individually responsible for ensuring a pharmacy's compliance with the DSCSA and other laws and ensuring the authenticity of medications and pedigrees purchased and sold by the pharmacy.
- 29. Defendant Lin Pharmacy Inc. d/b/a Makki Pharmacy is a retail pharmacy with a principal place of business in Queens, New York.
- 30. Defendant Samuel Yakubov is the principal of Lin Pharmacy Inc. d/b/a Makki Pharmacy and is a resident of New York.
- 31. Defendant Monica A. Ngo is the supervising pharmacist of Lin Pharmacy Inc. d/b/a Makki Pharmacy and a resident of New York. Among other things, supervising pharmacists are individually responsible for ensuring a pharmacy's compliance with the DSCSA and other laws and ensuring the authenticity of medications and pedigrees purchased and sold by the pharmacy.
- 32. Defendant Ascension Pharmacy Holdings I LLC d/b/a/ Mermaid RX and Ariel Pharmacy is a retail pharmacy with a principal place of business in Brooklyn, New York.
- 33. Defendant Alex Gelbinovich is the supervising pharmacist of Ascension Pharmacy Holdings I LLC d/b/a/ Mermaid Rx and Ariel Pharmacy and a resident of New York. Among other things, supervising pharmacists are individually responsible for ensuring a pharmacy's compliance with the DSCSA and other laws and ensuring the authenticity of medications and pedigrees purchased and sold by the pharmacy.

34. Collectively, Defendants Island Chemists, Inc. d/b/a Meadow Drugs & Surgical, Randolph Mohabir, V.L.S. Pharmacy Inc., Gopesh M. Patel, Lin Pharmacy Inc. d/b/a Makki Pharmacy, Samuel Yakubov, Monica A Ngo, Ascension Pharmacy Holdings I LLC d/b/a/Mermaid Rx and Ariel Pharmacy, and Alex Gelbinovich are referred to herein as the "Pharmacy Defendants."

D. DEFENDANTS NAMED IN SECOND AMENDED COMPLAINT

1. Leader Defendants

- 35. Defendant Paul Rosell is an individual residing in Miami, Florida. Rosell is a broker and salesman. Rosell is the registered agent and principal of Med-Connect Enterprises, LLC. As alleged herein, Rosell organized and led an enterprise dedicated to the sale of counterfeit Gilead HIV medication accompanied by false documentation.
- 36. Defendant Med-Connect Enterprises, LLC is a Florida limited liability corporation with a principal place of business in Florida. Its principal is Defendant Rosell.
- 37. Defendant Dhruv Ralhan is an individual residing in Saint Petersburg, Florida. Ralhan is the sole member of the limited liability corporation D & K Healthcare Solutions LLC. As alleged herein, Ralhan organized and led an enterprise dedicated to the sale of counterfeit Gilead HIV medication accompanied by false documentation.
- 38. Defendant D & K Healthcare Solutions LLC is a Wyoming limited liability corporation with a principal place of business in Florida. D & K Healthcare Solutions LLC is registered as a foreign corporation in the state of Florida. Its sole member is Defendant Dhruv Ralhan.
- 39. Defendant Venkata Srinivas Mannava is an individual residing in Carteret,
 New Jersey. Mannava is the registered agent, board of directors, and incorporator of DSP

Consulting Inc. As alleged herein, Mannava organized and led an enterprise dedicated to the sale of counterfeit Gilead HIV medication accompanied by false documentation.

40. Defendant DSP Consulting Inc. is a New Jersey corporation with a principal place of business in New Jersey. Its registered agent, board of directors, and incorporator is Defendant Venkata Srinivas Mannava.

2. Marketer Defendants

- 41. Defendant John Panagiotopoulos is an individual residing in Quebec, Canada. He is affiliated with Defendant Streamline RX LLC. Panagiotopoulos actively participated in the marketing and sale of counterfeit Gilead HIV products accompanied by counterfeit documentation.
- 42. Defendant Mike Zangari is an individual residing in Quebec, Canada. He is affiliated with Streamline RX LLC. Zangari actively participated in the marketing and sale of counterfeit Gilead HIV products accompanied by counterfeit documentation.
- 43. Defendant Riccardo Massana is an individual residing in Canada. He is affiliated with Streamline RX LLC. Massana actively participated in the marketing and sale of counterfeit Gilead HIV products accompanied by counterfeit documentation.
- 44. Defendant Streamline RX LLC is a Florida limited liability corporation with a principal place of business in Florida. Its registered agent and manager is Defendant Pavan Mantripragada.
- 45. Defendant Pavan Mantripragada is an individual residing in Tampa, Florida. Mantripragada is the registered agent and manager of Streamline RX LLC. As discovery will confirm, Mantipragada knowingly participated in the counterfeiting enterprise organized and led by the Leader Defendants.

3. Supplier Defendants

- a. Additional Boulevard Defendants
- 46. Defendant MFK Management LLC d/b/a Boulevard 9229 & 9229
 Boulevard is a New York corporation with a principal place of business in New York. MFK
 Management is closely affiliated with Boulevard 9229 LLC. Its owners of record are New York
 corporation Boulevard 9229 LLC (1%) and New York trust Castle Rock Irrevocable Trust
 (99%). Boulevard 9229 LLC's owner of record is Defendant Ishbay Shukurov. Castle Rock
 Irrevocable Trust's grantor and trustee is Defendant Peter Khaim, and its beneficiaries are
 Khaim's descendants. Defendant Peter Khaim is MFK Management's off-the-books principal.

b. Additional Synergy Defendants

- 47. Defendant Cesar Castillo Wholesalers LLC f/k/a Cesar Castillo LLC is a Colorado corporation with a principal place of business in Colorado. Its registered agent and principal is Defendant Julio Martin Gonzalez. Cesar Castillo Wholesalers LLC is affiliated with Defendants Synergy and Carlos Vega and participates in their counterfeiting operation.
- 48. Defendant DNS Distributor LLC is a Colorado limited liability company with a principal place of business in Colorado. Its registered agent and principal is Defendant Julio Martin Gonzalez. DNS Distributor LLC is affiliated with Defendants Synergy and Carlos Vega and participates in their counterfeiting operation.
- 49. Defendant Julio Martin Gonzalez is an individual residing in Colorado Springs, Colorado. Martin Gonzalez is the registered agent and principal of Cesar Castillo LLC and DNS Distributor LLC. As discovery will confirm, Martin Gonzalez knowingly participated in the counterfeiting activities of Synergy.

c. Omom Defendants

- 50. Defendant Omom Pharmaceuticals, Inc. is a Florida domestic corporation with a principal place of business in California. Its president and secretary is Defendant Luis D. Gonzalez Herrero.
- 51. Defendant Omom Wholesale Corp. is a California corporation with a principal place of business in California. Its CEO, secretary, CFO, and Director is Defendant Gustavo Fernandez.
- 52. Defendant Gustavo Fernandez is an individual residing in Miami, Florida. Fernandez is the CEO, secretary, CFO, and Director of Omom Wholesale Corp. Fernandez supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.
- 53. Defendant Luis D. Gonzalez Herrero is an individual residing in Hialeah, Florida. Gonzalez Herrero is the president and secretary of Omom Pharmaceuticals, Inc. Gonzalez Herrero supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.
- 54. Defendant Jordan Rodriguez Mato is an individual believed to reside in Texas. Rodriguez Mato is the agent and incorporator of Omom Wholesale Corp. Rodriquez Mato supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

d. Invicta Defendants

55. Defendant Invicta Wholesale Supply LLC is a Washington state limited liability company with a principal place of business in Washington. Its principal, president, and owner is Defendant Jorge Caba.

56. Defendant Jorge Caba is an individual residing in West Palm Beach, Florida. Caba is the principal, president, and owner of Invicta Wholesale Supply LLC. Caba supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

e. RXWholesale.com LLC Defendants

- 57. Defendant RXWholesale.com LLC is a New Jersey limited liability company with a principal place of business in New Jersey. Its president and accounts receivable contact is Defendant Gabriel Betesh.
- 58. Defendant Gabriel Betesh is an individual residing in Brooklyn, New York. Betesh is the president and accounts receivable contact for RXWholesale.com LLC. Betesh supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.
- 59. Defendant Daniel Gelbinovich is an individual residing in Brooklyn, New York. Gelbinovich is affiliated with RXWholesale.com LLC. Gelbinovich supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

f. Pharma Pac Defendants

- 60. Defendant Pharma Pac Wholesale Corp. is a California corporation with a principal place of business in California. Pharma Pac Wholesale Corp is also registered in the state of New Jersey with a principal place of business in New Jersey. Its CEO and secretary in California is Defendant Angel Toral. Its incorporator, board of directors, and agent in New Jersey is Defendant Angel Toral.
- 61. Defendant Angel Toral is an individual residing in Miami, Florida. Toral is the CEO and secretary of California registered Pharma Pac Wholesale Corp. Toral is the incorporator, board of directors, and agent of New Jersey registered Pharma Pac Wholesale

Corp. Toral supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

g. Gentek Defendants

- 62. Defendant Gentek LLC is a Connecticut limited liability company with a principal place of business in Connecticut. Its manager and CEO is Defendant Edel Reyes.
- 63. Defendant Edel Reyes is an individual residing in Hialeah, Florida. Reyes is the manager and CEO of Gentek. Reyes supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

h. Rapid's Tex Defendants

- 64. Defendant Rapid's Tex Whole Sales Corp. is a Texas corporation with a principal place of business in Texas. Rapid's Tex is owned and operated by Defendant John Santos.
- 65. Defendant John Santos is an individual residing in Houston, Texas.

 Santos owns and operates Defendant Rapid's Tex. Santos supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

i. CM Pharmaceutical Defendants

- 66. Defendant CM Pharmaceutical LLC is an Alabama limited liability company with a principal place of business in Alabama. Its manager and principal are Defendants Jeffrey W. Gafnea and Robert W. Gafnea, respectively.
- 67. Defendant Jeffrey W. Gafnea is an individual residing in Tuscaloosa, Alabama. Jeffrey W. Gafnea is the manager of CM Pharmaceutical LLC. Jeffrey W. Gafnea supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

68. Defendant Robert W. Gafnea is an individual residing in Alabaster,
Alabama. Robert W. Gafnea is the principal of CM Pharmaceutical LLC. Robert W. Gafnea supervised, ratified, and/or personally participated in the trafficking of counterfeit Gilead medications.

j. Scripts Defendants

- 69. Defendant Scripts Wholesale Inc. is a New York corporation with a principal place of business in New York. Its principal is Defendant Steven Diamantstein. Scripts Wholesale Inc is a brick-and-mortar distributor that sells counterfeit Gilead medication.
- 70. Defendant Steven Diamantstein is an individual residing in Brooklyn, New York. Diamanstein is the principal of NER250 LLC d/b/a Scripts Wholesale Inc., USDV Pharma LLC, and Scripts Wholesale Inc. Diamanstein supervised, ratified, and/or personally participated in the trafficking of counterfeit HIV medications.
- 71. Defendant USDV Pharma LLC is a New York limited liability corporation with a principal place of business in New York. Its principal is Defendant Steven Diamantstein.
- 72. Defendant NER250 LLC d/b/a Scripts Wholesale is a New York limited liability corporation with a principal place of business in New York. Its principal is Defendant Steven Diamantstein.
- 73. Defendant Jeff Beetley is a resident of Tennessee. Beetley holds himself out as the CEO of USDV Pharma. Beetley is also a Scripts employee whose job duties included selling Scripts' purported Gilead mediations.

k. The Medicine Shoppe Defendants

74. Defendant Maryland Pharmacies Inc. d/b/a The Medicine Shoppe #1802 is a Maryland corporation with a principal place of business in Maryland. Its resident agent and authorized person is Defendant Sekar Venkatesh.

- 75. Defendant PrimeRX Inc. is a Maryland corporation with a principal place of business in Maryland. Its principal is Defendant Sekar Venkatesh. PrimeRX Inc. is a New York-licensed pharmaceutical wholesaler.
- 76. Defendant Sekar Venkatesh is an individual residing in Maryland.

 Venkatesh is the principal of PrimeRX Inc and resident agent and authorized person of Maryland

 Pharmacies Inc. d/b/a The Medicine Shoppe #1802. Venkatesh supervised, ratified, and/or

 personally participated in the trafficking of counterfeit Gilead medications.

4. The Asset-Holder Defendants

- a. Make It Happen Defendants
- 77. Defendant Make It Happen Marketing Inc. is a New York corporation with a principal place of business in New York. Its principal is Defendant Quan Hernandez. As alleged herein, Make It Happen Marketing Inc. received proceeds of counterfeit Gilead medications from the Boulevard Defendants.
- 78. Defendant Quan Hernandez is an individual residing in New York, New York. Hernandez is the principal of Make It Happen Marketing Inc.

b. Titan Distribution & Tidy Garages Defendants

- 79. Defendant Titan Distribution & Services LLC is a Florida limited liability company with a principal place of business in Florida. Its principal is Defendant Gabriel Delgado Ramirez. Titan Distribution & Services LLC received proceeds of counterfeit Gilead medications from the Omom Defendants for the purpose of laundering the funds and funneling them back to the suppliers of the counterfeits and the beneficiaries of the counterfeiting enterprise.
- 80. Defendant Tidy Garages LLC is a Florida limited liability company with a primary place of business in Florida. Its registered agent and manager is Defendant Gabriel

Delgado Ramirez. Tidy Garages LLC received proceeds of counterfeit Gilead HIV medication from the Omom Defendants for the purpose of laundering the funds and funneling them back to the suppliers of the counterfeits and the beneficiaries of the counterfeiting enterprise.

81. Defendant Gabriel Delgado Ramirez is an individual residing in Miami, Florida. Delgado Ramirez is the principal of Titan and registered agent and manager of Tidy Garages LLC. As discovery will confirm, Delgado Ramirez knowingly participated in the counterfeiting enterprise described herein.

c. ASB and Silverline Defendants

- 82. Defendant ASB Wholesale Distributors LLC is a Florida limited liability company with a principal place of business in Florida. Its registered agent and principal is Defendant Alberto Alonso Diaz. ASB Wholesale Distributors LLC received proceeds of counterfeit Gilead HIV medication that were routed from the Omom Defendants through Titan Distribution & Services LLC for the purpose of laundering the funds and funneling them back to the suppliers of the counterfeits and the beneficiaries of the counterfeiting enterprise.
- 83. Defendant Silverline Pharma Logistics LLC is a Florida limited liability company with a principal place of business in Florida. Its registered agent and principal is Defendant Alberto Alonso Diaz. Silverline Pharma Logistics LLC received proceeds of counterfeit Gilead HIV medication that were routed from the Omom Defendants through Titan Distribution & Services LLC, for the purpose of laundering the funds and funneling them back to the suppliers of the counterfeits and the beneficiaries of the counterfeiting enterprise.
- 84. Defendant Alberto Alonso Diaz is an individual residing in Miami, Florida. Alonso Diaz is the registered agent and principal of ASB Wholesale Distributors LLC and Silverline Pharma Logistics LLC. As discovery will confirm, Alonso Diaz knowingly participated in the counterfeiting enterprise described herein.

d. JM Smith Distribution Corp. Defendants

- 85. Defendant JM Smith Distribution Corp. is a New Jersey corporation with principal place of business in New Jersey. Its principal is Defendant Carlos Hernandez. JM Smith Distribution Corp received proceeds of counterfeit Gilead HIV medication from the Invicta Defendant, for the purpose of laundering the funds and funneling them back to the suppliers of the counterfeits and the beneficiaries of the counterfeiting enterprise.
- 86. Defendant Carlos Hernandez is an individual residing in Hackensack, New Jersey. Hernandez is the principal and incorporator of JM Smith Distribution Corp. As discovery will confirm, Hernandez knowingly participated in the counterfeiting enterprise described herein.

E. RELIEF DEFENDANTS

87. Relief Defendant 5 Continental LLC ("Continental") is the nominal owner of real property located at 107-27 71st Ave. and 107-29 71st Ave., Forest Hills, New York (the "71st Avenue Property"), which Continental purchased on September 11, 2020 for \$10,600,000. Continental was organized on April 1, 2020, five months before the purchase of the 71st Avenue Property. In public filings, Defendant Khaim's wife, Oksana Politiva, is listed as the organizer of Continental, with no other officers or owners identified. Ms. Politiva signed the deed for the 71st Avenue Property. In reality, the purchase of the 71st Avenue Property was orchestrated entirely by Defendant Khaim, who among other things negotiated the terms of the purchase, provided the funds for the purchase, and instructed his real-estate lawyer to effect the purchase. Defendant Khaim caused the 71st Avenue Property to be purchased with the illicit proceeds of his counterfeiting, and the purpose of the purchase was to launder the proceeds of the counterfeiting and maintain those illicit assets nominally in the name of the shell company Continental.

- agreement claiming to have fully funded Continental's purchase of 71st Avenue Property. The supposed mortgage is a sham. AP Funding LLC was created just a week before the purchase of the 71st Avenue Property closed. The mortgage agreement is unsigned and contains incorrect information about the purchase. Neither the mortgage agreement nor any other public documents concerning AP Funding LLC list any individuals associated with the company. However, AP Funding LLC lists a business address of 67-43 Woodhaven Boulevard, Queens, which is the same address used by several other Khaim shell companies, including Defendant MFK Management and A&P Holding Group, another entity that uses the initials of the first names of Defendant Peter Khaim and his brother (and criminal co-defendant) Arkadiy. AP Funding LLC was founded by or at the direction of Defendant Khaim for the purpose of laundering the proceeds of the counterfeiting, including by facilitating the straw-man purchase of the 71st Avenue Property by Continental.
- to 453 Willis Ave. and 441 to 459 Willis Ave., Bronx, New York (the "Willis Avenue Property"), which 441 Willis Ave LLC purchased on September 20, 2021 for \$5,200,000. 411 Willis Ave LLC was organized the month before the purchase of the Willis Avenue Property, on August 3, 2021, by a third-party corporate services vendor. Defendant Khaim's mother, Riva Musheyeva, signed the deed for the Willis Avenue Property. In reality, the purchase of the Willis Avenue Property was orchestrated entirely by Defendant Khaim, who among other things negotiated the terms of the purchase, provided the funds for the purchase, and instructed his realestate counsel to effect the purchase. Defendant Khaim caused the Willis Avenue Property to be purchased with the illicit proceeds of his counterfeiting, and the purpose of the purchase was to

launder the proceeds of the counterfeiting and maintain those illicit assets nominally in the name of the shell company 411 Willis Ave LLC.

- property located at 80-74 188th St., Hollis Hills, New York (the "188th Street Property"), which La Vie purchased on February 12, 2021, for \$2,100,000. Defendant Khaim organized La Vie and signed the deed for the 188th Street Property. The purchase of the Willis Avenue Property was orchestrated entirely by Defendant Khaim, who among other things negotiated the terms of the purchase, provided the funds for the purchase, and instructed his real-estate counsel to effect the purchase. Defendant Khaim caused the Willis Avenue Property to be purchased with the illicit proceeds of his counterfeiting, and the purpose of the purchase was to launder the proceeds of the counterfeiting and maintain those illicit assets nominally in the name of the shell company La Vie.
- 91. Relief Defendant AG Worldwide Pharma Sales, Inc. ("AG Worldwide") is a lookalike shell company created to imitate the identity of Defendant Worldwide Pharma. Worldwide Pharma's owner, Defendant Brosius, caused AG Worldwide to be founded under the nominal ownership of one of his employees, Garrett Mellott. Defendant Brosius then instructed Safe Chain to pay his cut of the counterfeiting proceeds, which normally would have been paid to Worldwide Pharma, to be paid to AG Worldwide instead including payments for counterfeits that were sold before AG Worldwide even existed. The purpose of AG Worldwide's creation was to transfer and conceal Defendant Brosius's and Worldwide Pharma's the illicit counterfeiting proceeds.
- 92. Relief Defendant Swetha Ketineni is the wife of Defendant Mannava. Ms. Ketineni was present on October 18, 2021 when Gilead executed this court's Seizure Order and

served Defendant Mannava with the Asset Freeze Order at their shared residence, and received actual notice of this court's asset freeze. In blatant violation of that order, Defendant Mannava transferred over \$3.3 million to Ms. Ketineni, beginning on the day of the seizure itself and continuing over the following several days. All of the \$3.3 million transferred to Ms. Ketineni were the illicit proceeds of the counterfeiting, and included funds from Defendant Mannava's company, DSP. Ms. Ketineni then quickly dissipated the funds her husband had illegally transferred to her, including by sending it to individuals in India and by transferring over a million dollars to a shell corporation she founded, Babashiloh Enterprises LLC.

93. Relief Defendant Babashiloh Enterprises LLC ("Babashiloh") was formed on October 29, 2021 in New Jersey by Ms. Ketineni, shortly after Defendant Mannava unlawfully transferred over \$3.3 million in counterfeiting proceeds to Ms. Ketineni. Within days of founding Babashiloh, Ms. Ketineni transferred at least \$1.1 million of those unlawfully transferred funds to Babashiloh. Ms. Ketineni's purpose in creating Babashiloh was to further dissipate and conceal the proceeds of the counterfeiting, which were already the subject of this Court's freeze order.

JURISDICTION AND VENUE

- 94. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 1121(a), 1331, 1338, and 1367 and general principles of ancillary and pendent jurisdiction.
- 95. The Court has personal jurisdiction over each of the Defendants because each of the Defendants has sufficient minimum contacts with New York and with this District so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

- 96. As alleged herein, many Defendants are residents of New York and of this District. For example, the Boulevard Defendants all reside in this District. The Pharmacy Defendants are all New York pharmacies and their principals and supervising pharmacists who are named as defendants are all residents of New York. The Scripts Defendants are also located in this District and their principal resides in this District.
- 97. Several Defendants, including the Safe Chain Defendants and the PharmaPac Defendants, have consented to personal jurisdiction and venue in this District.
- 98. As alleged herein, all Defendants transacted business in New York and committed tortious acts in New York in connection with the counterfeiting business described herein. For example, Safe Chain and Worldwide Pharma sold, and conspired together to sell, counterfeits to pharmacies in New York City. ProPharma, through its principal Ellis, advertises that it sells throughout the United States, maintains active licensure in New York as an out-of-state pharmaceutical wholesaler for the purpose of selling pharmaceutical products in New York, and has sold infringing products into New York. The Synergy Defendants, including Defendant Carlos Vega personally, travelled to New York to conduct the counterfeiting business alleged herein and transmitted the majority of their counterfeiting revenues to New York entities for the purposes of laundering the proceeds in New York and/or purchasing counterfeits in New York.
- 99. As alleged herein, many of the Relief Defendants received the proceeds of counterfeiting including directly from the purchases and sales to and from New York state and this district.
- 100. The Leader Defendants, the Marketer Defendants, and the Supplier Defendants (including Gentek and RXWholesale.com LLC) conspired to sell counterfeit Gilead medications to the Scripts Defendants in this District. These Defendants also conspired to sell

counterfeit Gilead HIV medication to New York pharmacies on behalf of Scripts, Safe Chain, and ProPharma. These Defendants also conspired to launder money and/or to source counterfeits in New York and in this District.

- 101. The Medicine Shoppe Defendants possess a license to sell pharmaceutical products in New York. These Defendants negotiated directly with the Boulevard Defendants to purchase counterfeit Gilead HIV medication in New York. Knowing that the products were counterfeit, The Medicine Shoppe Defendants conspired with the Boulevard Defendants to distribute counterfeit Gilead HIV medication.
- 102. This Court also has personal jurisdiction over certain Defendants pursuant to 18 U.S.C. § 1965(d) because these Defendants are liable for substantive RICO violations under 18 U.S.C. § 1962(c). These Defendants are identified in paragraph 376 below.
- Defendant knowingly aided and abetted the violation of an asset freeze order properly issued by this Court. Moreover, Relief Defendant AG Worldwide, in concert with Defendants Brosius and Worldwide Pharma, participated in the sale of counterfeits to pharmacies in New York and received funds from such sales. And as alleged herein, several of the Relief Defendants are New York entities and New York residents, including 5 Continental LLC, AP Funding LLC, 441 Willis Ave LLC, and La Vie Jewels of NY LLC.
- 104. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(b) because, as alleged above, multiple Defendants are located in this District, multiple Defendants reside in this District, multiple Defendants have their principal place of business in this District, multiple Defendants sold counterfeit products into this District, multiple Defendants conspired to

operate a counterfeiting operation that sold counterfeit products into this District, and because a substantial part of the events giving rise to Gilead's claims occurred in this District.

105. Venue is also proper over certain Defendants pursuant to 18 U.S.C. § 1965 because these Defendants are liable for substantive RICO violations. These Defendants are identified in paragraph 376 below.

FACTUAL ALLEGATIONS

A. GILEAD'S HIV AND OTHER MEDICATIONS

- 106. For more than three decades, Gilead has strived to create a healthier world for all by delivering innovative therapeutics that aim to prevent, treat, or cure life-threatening diseases. Gilead relentlessly pursues advancements in science with the goal of bringing to patients around the world treatments that improve care in areas of unmet medical needs.
- 107. Gilead has transformed care for people living with serious diseases, *e.g.*, HIV and hepatitis C, developing pioneering medicines including the world's first single tablet regimen to treat HIV, the first prophylactic medicine to prevent HIV infection, and four hepatitis C therapies.
- 108. BIKTARVY® is a complete, one-pill, once-a-day prescription medication used to treat HIV. Developed by Gilead and first approved by the FDA in 2018, BIKTARVY® is a single-tablet combination medicine for the treatment of HIV-1 infection, combining the unboosted integrase strand transfer inhibitor (INSTI) bictegravir with Gilead's dual nucleoside reverse transcriptase inhibitor (NRTI) backbone of emtricitabine and tenofovir alafenamide, the components of Gilead's DESCOVY®.
- 109. BIKTARVY® has a demonstrated long-term efficacy and safety profile, has few drug interactions and side effects, and a high barrier to developing drug resistance.

- 110. Although BIKTARVY® does not cure HIV, when taken every day as prescribed, it can lower the amount of virus in a patient's blood to undetectable levels. In addition to halting the progression of HIV, research shows that having undetectable levels of the virus prevents transmission of HIV through sex, protecting a patient's sexual partners from possible transmission.
- 111. BIKTARVY® also can help increase the number of a patient's CD4 T-cells, which are an important part of a person's immune system. HIV attacks and destroys CD4 T-cells, which decreases a patient's ability to fight off other infections and increases the risk of a patient contracting an opportunistic infection, which could lead to serious illness or death.
- 112. One of the most significant developments in the fight against HIV is the development of drugs for pre-exposure prophylaxis, or PrEP: a method of HIV prevention whereby individuals who are HIV-negative but at-risk for HIV infection proactively take medication on an ongoing basis to decrease their risk of acquiring HIV through sex.
- 113. DESCOVY® is a therapy developed and manufactured by Gilead that can be taken for PrEP. The drug comes in the form of a tablet. The dosage in the FDA approved label is one tablet per day.
- 114. When taken as indicated, DESCOVY® is highly effective at preventing HIV-1 infection in individuals exposed to the virus.
- 115. DESCOVY® was approved by the FDA for PrEP in 2019. It has been an instrumental part of preventing the spread of HIV in areas in the United States where there is a high prevalence of HIV.
- 116. Gilead has used and currently is using the Gilead Marks and the Gilead Trade Dress in commerce in connection with its sale of medications, and plans to continue such

use in the future. Gilead prominently displays the Gilead Marks in its advertising and promotional materials.

117. Gilead has engaged and continues to engage in activities designed to promote its medications and the business and goodwill associated with its trademarks, and to expand the use and reputation of its trademarks, trade dress, logos, copyrights, and property throughout the United States. All of these trademarks and trade dress symbolize business goodwill of Gilead and are invaluable assets to Gilead.

B. DEFENDANTS' COUNTERFEIT HIV AND OTHER MEDICATIONS

- 118. Gilead learned of Defendants' counterfeiting operation through a series of patient and pharmacy complaints that were reported to Gilead. In the past several months, Gilead has received multiple complaints from patients and pharmacies about bottles of Gilead HIV medications that were sold by Safe Chain and that, when opened, were actually filled with an entirely different drug.
- HIV medications that were the subject of these patient or pharmacy complaints. But, to date, Gilead has been able to acquire several bottles of counterfeit HIV medications that Safe Chain sold to U.S. pharmacies. Gilead's in-house experts examined the bottles and their contents and determined the products to be counterfeit. Gilead also sent the bottles to an outside laboratory who performed analyses of the bottles, the tamper-proof seals and the adhesives used to affix them, and the tablets inside the bottles. The outside lab also confirmed that the HIV medications sold by Safe Chain were counterfeit.
- 120. Authentic Gilead HIV medication is FDA approved for sale only in Gilead's original, sealed manufacturer bottles: it cannot be sold or dispensed in generic pharmacy vials. The lip of each authentic bottle is covered with a foil tamper-evident seal,

which is covered by a screw-on lid. Safe Chain's counterfeits appeared to use authentic Gilead bottles that once contained authentic Gilead medication. The original foil on the bottles had been stripped away, the authentic medication removed and replaced with foreign medication, and then a replica of the tamper-evident seal was used to re-seal the bottle. Traces of the original tamper-proof seal remained in the grooves of the counterfeit bottles and were visually distinguishable from the replica seal. Lab testing confirmed that both the replica seal and the adhesive used to affix it did not match the original, authentic foil and adhesive used on authentic Gilead product.

- 121. The outside laboratory's testing also confirmed what was apparent to the medical professionals and in-house experts who examined the counterfeits: that the tablets inside the bottle were not the Gilead medication listed on the bottle. In one instance, the counterfeit bottle contained a generic over-the-counter analgesic. But the most common contents of the tested counterfeits was quetiapine fumarate ("quetiapine"), a non-Gilead medication that is marketed under the brand name SEROQUEL XR® and is also available as a generic.
- 122. Quetiapine is a prescription anti-psychotic medication with a number of known serious potential side effects. Quetiapine can very commonly cause a strong sedated state or drowsiness. As noted on the FDA labelling for the drug, these effects are especially acute for first-time users of the drugs. One patient who unknowingly took SEROQUEL XR® after receiving a counterfeit bottle of BIKTARVY® reported that the patient could not speak or walk afterwards. Patients who are prescribed quetiapine are warned against driving or operating machinery.
- 123. Quetiapine also poses serious potential dangers to patients with common health conditions, such as high blood pressure, diabetes, and low white blood counts, whose conditions must be closely monitored while taking quetiapine.

- 124. Because of its potency, the FDA-approved labelling for quetiapine recommends that some new patients be given a small dose 50 milligrams a day for many conditions that can be increased over time as the patient's physician tracks any side effects and monitors the patients' reaction to the drug. The counterfeit Gilead HIV medication contained 300-milligram tablets of quetiapine.
- 125. Of course, patients who ingest quetiapine from a counterfeit bottle of HIV medication have no idea that they are taking a medication with these potential side effects and receive no warning of the possible consequences of doing so. They have no idea they are not supposed to drive, operate heavy machinery, or engage in other activities where sedation or drowsiness are dangerous, and as a result are placed in grave danger of injury or death.
- 126. Patients who receive the Defendants' counterfeits may not receive their prescribed HIV or other medications. For patients treating HIV infection, it is very important that the patient take their prescribed Gilead medication once a day, every day. If a patient skips doses for even a short period of time, the patient faces the risk that the patient's viral load that is, the amount of HIV in their blood will increase. Viral rebound can have severe consequences. Over time, it can weaken the patient's immune system and increase the possibility of infections; it can result in progression of the disease and lead to the development of AIDS; and if patients are not virally suppressed they may transmit the virus to their sexual partners.
- 127. Patients taking DESCOVY for PrEP® must also take the medication regularly as prescribed to receive the prophylactic benefits of the drug. DESCOVY for PrEP® is indicated only for certain individuals at risk for HIV infection. A patient who unknowingly

discontinues their DESCOVY® regimen because they have received counterfeit medication would be at risk for contracting HIV while still believing they are being protected from infection.

C. DEFENDANTS' COUNTERFEIT PEDIGREES

- 128. Under the Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. §§
 360eee *et seq.*, every sale or transfer of a prescription drug must be accompanied with a record showing the chain of all sales or transfers of that drug, going back to the manufacturer. In the industry, this is known as the drug's "pedigree," and is also referred to as the drug's DSCSA documentation or "T3" documentation standing for the three "Ts" of transaction information, transaction history, and transaction statement that must be included with the pedigree.
- 129. The FDA's website states that the purpose of the DSCSA's tracing requirements is to "enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit[.]"
- 130. Counterfeit bottles of HIV and other medications cannot have valid pedigrees. In order to sell their counterfeit medications, the Defendants created and utilized fake pedigrees that fraudulently represented that the drugs could be traced back to an authentic sale from Gilead.
- 131. Gilead obtained the purported pedigrees for several counterfeit bottles of Gilead HIV and other medications sold by Defendants, including Safe Chain, ProPharma, Synergy, and Boulevard. Those pedigrees were also fake, many of them obviously so.
- 132. In the United States, the only distributors to which Gilead sells its HIV and other medications are Gilead authorized distributors. This is a well-known fact in the industry, and is consistent with the practices of other major pharmaceutical manufacturers.

¹ https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

Gilead has sixteen U.S. authorized distributors for HIV medications, and their names are publicly posted on Gilead's website. Defendants are aware that Gilead sells HIV medications only through those Gilead authorized distributors.

- detectable falsehood: that Gilead had initially sold the medication to a distributor other than an authorized distributor. Other pedigrees for the counterfeits did list an authorized distributor as the first purchaser of the drug, and then claimed the drug was sold from there to one or more distributors before it was purchased by Safe Chain. Gilead's internal records confirm that Gilead had not sold the specific lots of the medication to the authorized distributor listed on the pedigree. Gilead also confirmed with the authorized distributors that the pedigrees were false.
- 134. While Gilead has only been able to recover a sample of the counterfeits that have been reported to it, as part of its investigation Gilead has received copies of pedigrees for thousands of bottles of Gilead HIV and other medications trafficked by the Defendants in this action. Those pedigrees are fake: they fraudulently list an initial sale made by Gilead that did not occur. Every one of those bottles is an illegitimate product and pursuant to the DSCSA must be quarantined and cannot lawfully be sold.
- comes with a pedigree that accurately discloses when and to whom Gilead sold that bottle. The pedigree is part of the product that Gilead sells. For Gilead, the pedigrees are anti-counterfeiting measures and also play other important internal quality-control functions. For the distributors, pharmacies, and patients that buy Gilead's HIV and other medications, authentic pedigrees that accurately disclose the original sale of the product are an important feature of Gilead's products that guarantee the medication's authenticity and safety. Bottles of Gilead medication that have

fake or altered pedigrees, such as those that do not list Gilead's original, authentic sale of the medication, are materially different from authentic Gilead product as Gilead sells it in U.S. commerce.

D. SAFE CHAIN'S WILLFUL SALE OF COUNTERFEIT HIV MEDICATIONS AFTER BEING REPEATEDLY INFORMED IT WAS SELLING COUNTERFEITS

- 136. Safe Chain holds itself out to be a legitimate pharmaceutical distributor, specializing in HIV medications among a few other areas. In reality, Safe Chain is a willful trafficker of counterfeit HIV and other medications, and has knowingly put an untold number of patients' health and lives at risk in order to make an illicit profit.
- 137. Over the past several months, Gilead received report after report of counterfeit Gilead HIV medications from pharmacies and customers, all of which Safe Chain had sold to the dispensing pharmacy. Gilead initially treated Safe Chain as an unwitting distributor of counterfeits, and attempted to work cooperatively with the company to address the problem. Legitimate distributors who learn they have sold counterfeits let alone bottles of counterfeit HIV medications that actually contain a high-dose antipsychotic will do everything they can to ensure they do not sell any more counterfeits, and assist the manufacturer in tracking down the source of the counterfeits. Safe Chain did the opposite.
- 138. In response to Gilead's communications, Safe Chain engaged in a campaign of delay and obfuscation, hiding its suppliers and refusing to provide Gilead with crucial information about the counterfeits. Meanwhile, Safe Chain continued to buy thousands of bottles of Gilead medication, all of them with fake pedigrees, from the same counterfeit suppliers, even after Safe Chain had been informed that these suppliers were selling counterfeit Gilead HIV medications.

1. Safe Chain Is Notified It Is Selling Counterfeits but Obstructs Gilead's

Investigation and Continues Purchasing from Its Counterfeit Supplier

- Gilead and Safe Chain that a patient had returned a bottle of BIKTARVY® that had foreign medication inside. The pharmacy had purchased that counterfeit from Safe Chain. Knowing that the pharmacy had already reported the counterfeit to Gilead, Safe Chain's co-founder Charles Boyd wrote to Gilead to disclose White Cross Pharmacy's report. On September 11, 2020, Gilead asked Safe Chain to identify who had supplied this counterfeit to Safe Chain, but Safe Chain refused to do so.
- 140. In November 2020, Gilead again asked Safe Chain to provide the pedigree and identify the supplier from whom Safe Chain had purchased the counterfeit. Safe Chain refused, stating only that it had purchased the counterfeits from an "authorized trading partner." Gilead responded that was "wholly inadequate," noting that Gilead needed that information "to determine how this illegitimate product made its way into the supply chain."
- 141. Between August 2020 and early February 2021, Gilead asked Safe Chain on at least five different occasions to produce the pedigree for the counterfeit it sold to White Cross Pharmacy, but each time Safe Chain either refused or ignored the request.
- 142. In October 2020, Safe Chain received another report of counterfeit BIKTARVY® from a different pharmacy Defendant The Medicine Shoppe in Maryland. The counterfeit BIKTARVY® bottle was actually filled with 300 mg tablets of SEROQUEL XR®. But this time, Safe Chain knew that the pharmacy had not immediately reported the counterfeit to Gilead. Hoping to avoid detection, Safe Chain tried to dissuade the pharmacy from reporting the incident. In an email to The Medicine Shoppe, Safe Chain's Director of Compliance suggested that instead of "contact[ing] Gilead," the pharmacy should "return[] it to us, and then let us send it back." Safe Chain never did report this counterfeit to Gilead.

- 143. Gilead only learned about this October 2020 counterfeit report because in February 2021, The Medicine Shoppe received from a patient *another* report of counterfeit BIKTARVY® that the pharmacy had purchased from Safe Chain. Gilead promptly interviewed The Medicine Shoppe. During that interview, the pharmacy disclosed its October 2020 counterfeit report to Safe Chain, stating that it had returned the counterfeit bottle to Safe Chain but heard nothing back.
- 144. When Gilead confronted Safe Chain about the October 2020 counterfeit report from The Medicine Shoppe, Safe Chain claimed it *had* reported that incident to Gilead, and that Gilead was at fault for not responding to Safe Chain's report. That claim was false. Gilead immediately demanded, and later repeated its demand, that Safe Chain substantiate its claim that it had reported the October 2020 incident. Safe Chain never provided any such corroboration, because it never made any such report to Gilead.
- 145. Each of the three known examples of counterfeit BIKTARVY® that were reported to Safe Chain between August 2020 and early February 2021 had been supplied to Safe Chain by Gentek LLC ("Gentek"), located in Stamford, Connecticut. During that period, Safe Chain worked to conceal the counterfeit reports from Gilead, and when Gilead learned about them, refused to provide pedigrees or identify its counterfeit supplier. During that same time period from the time Safe Chain was first directly told that the Gilead medication it sourced from Gentek was counterfeit to the time Safe Chain revealed Gentek's identity to Gilead Safe Chain purchased over 8,000 bottles of Gilead HIV medications from Gentek for over \$20 million, including over 3,000 bottles of BIKTARVY®, all while knowing that Gentek was selling dangerous counterfeits.

2. Safe Chain Provides Fake Pedigrees to Gilead

- 146. Realizing that Gilead's counterfeit investigation was escalating and that it would not be possible to stonewall and obstruct the investigation indefinitely, on February 22, 2021, Safe Chain finally provided the pedigree for the counterfeit BIKTARVY® that White Cross Pharmacy had reported *six months* prior. Safe Chain also provided pedigrees one from Safe Chain and one from its supplier for the two counterfeit bottles of BIKTARVY® that were reported by The Medicine Shoppe. Each of the pedigrees indicated that Safe Chain had purchased the counterfeit from Gentek. Each pedigree also indicated that Gentek had purchased the counterfeit from Drogueria Betances, a Gilead authorized distributor located in Puerto Rico.
- 147. Gilead determined that those pedigrees were fake. Gilead did not sell the lot numbers listed on the pedigrees to Drogueria Betances. And Gilead confirmed with Drogueria Betances that Gentek was not one of its customers.
- 148. Gilead has learned that Safe Chain not only provided Gilead with fake pedigrees, but that Safe Chain altered those pedigrees by adding false information immediately before sending them to Gilead.
- 149. Gilead obtained from Safe Chain's customer, Defendant The Medicine Shoppe, the pedigree that Safe Chain sent to the Medicine Shoppe in the normal course of business *i.e.*, at the time it sold the counterfeit bottle to the pharmacy. The pedigree that Safe Chain sent to its customer and the pedigree it sent to Gilead should, of course, be identical. They are not, as shown in the figure below:

Pedigree that Safe Chain sent to pharmacy

SAFE CHAIN SOLUTIONS, LLC

(TI) Transaction Information

Drug Supply Chain Security Act Document Doc# 00000019202

Drug Name, Strength, Dosag BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01	e Form, Container Size:	Reference Number: 01140811 Document Type: Invoice		
Lot Number Quan	tity Unique Serial #	Reference Date: 01/08/21		
6400505A 3	Orlique Serial #	Reference Date.		
CDGXBA 1				
CCZCFA 1				
(TH) Transaction History Manufacturer's Name: GILEAD SCIENCES Manufacturer's Information:				
SOLD TO: Name: GENTEK LLC Address: 45 CEDAR ST U STAMFORD CT (Date Purchased & Ref :	Phone: 203-274-3527	SHIPPED TO:		
SOLD TO: Name: SAFE CHAIN SO Address: 822 CHESAPEA CAMBRIDGE MI Date Purchased & Ref :	KE DR D 21613	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref: 0109021 RC#016349		
SOLD TO: Name: MEDICINE SHO Address: 10313 GEORGIA SILVER SPRING Date Purchased & Ref :	A AVENUE #101	SHIPPED TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref: 0.101821 0.1536758001		
SOLD TO: Name: Address:		SHIPPED TO: Name: Address:		
Date Purchased & Ref :		Date Received & Ref :		
SOLD TO:		SHIPPED TO:		
Name:		Name:		
Address:		Address:		
Date Purchased & Ref :		Date Received & Ref :		

Pedigree that Safe Chain sent to Gilead

SAFE CHAIN SOLUTIONS, LLC

Quantity Unique Serial #

(TI) Transaction Information

50/200/25 MG NDC: 61958-2501-01

Lot Number

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT,

Drug Supply Chain Security Act Document Doc# 00000019202

Reference Number: Document Type:

Reference Date:

01140811

01/08/21

6400505A	3		
CDGXBA	1		
CCZCFA	1		
			1
(TH) Transaction	n History		
. ,	ame: GILEAD SO	TENCES INC	
Manufacturer's in	formation: 1800 WHF	ELER AVENUE LA VE	RNE CA 91750
SOLD TO:			SHIPPED TO:
Name: DROGUERIA BETANCES			Name: DROGUERIA BETANCES
Address: LUIS MUNOZ MARIN AVE			Address: LUIS MUNOZ MARIN AVE
CAGU	AS PR 00725		CAGUAS PR 00725
Date Purchased	& Ref: 10/05/20	85160	Date Received & Ref: 10/05/20 85160
SOLD TO: Name: GENTE	-K110		SHIPPED TO:
Address: 45 CEI			Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3
	ORD CT 06902		STAMFORD CT 06902
	& Ref: 10/06/20	2719	Date Received & Ref : 10/06/20 2719
Date Purchaseu a	x Rei : 10/06/20	2/19	Date Received & Ref : 10/00/20 2717
SOLD TO:			SHIPPED TO:
Name: SAFE CHAIN SOLUTIONS, LLC			Name: SAFE CHAIN SOLUTIONS
Address: 822 Ch			Address: 822 CHESAPEAKE DR
	RIDGE MD 21613		CAMBRIDGE MD 21613
Date Purchased	& Ref: 01/07/21	PO#01211389	Date Received & Ref : 01/08/21 RC#016349
SOLD TO:			SHIPPED TO:
Name: MEDICINE SHOPPE #1802			Name: MEDICINE SHOPPE #1802
Address: 10313 GEORGIA AVENUE #101			Address: 10313 GEORGIA AVENUE #101
	R SPRING MD 20902		SILVER SPRING MD 20902
Date Purchased	& Ref : 01/08/21	01S36758001	Date Received & Ref : 01/08/21 01S36758001
SOLD TO:			SHIPPED TO:
Name:			Name:
Address:			Address:
Date Purchased & Ref :			Date Received & Ref :

- 150. The pedigree that Safe Chain originally sent to The Medicine Shoppe listed an initial sale directly from Gilead to Gentek an obvious red flag, because Gentek is not a Gilead authorized distributor. That original pedigree also omitted basic details, such as Gilead's address and the date and reference number for the supposed initial sale from Gilead to Gentek.
- 151. But the pedigree that Safe Chain later sent to Gilead had an additional transaction added to the sales chain: a purported initial sale from Gilead to Drogueria Betances, the Gilead authorized distributor. Moreover, the information missing on the original pedigrees Gilead's address, date of initial sale, and reference number for initial sale are now filled in (fraudulently, because those initial sales never happened). In other words, the original pedigrees, which were immediately recognizable as fake, had been altered to include information that was also fake, but was harder to recognize as such.

152. Safe Chain sent both sets of pedigrees as PDF files that contain metadata showing the date they were created. Safe Chain created the pedigree it sent to The Medicine Shoppe on January 8, 2021, the day it sold the bottles to the pharmacy, as would be expected. But Safe Chain created the altered pedigree on February 19, 2021 – meaning the altered pedigree was created outside the normal course of business, just days before Safe Chain sent it to Gilead.

3. Safe Chain's Willful Purchases of Counterfeits from Defendant Boulevard

- verify the expiration date on a bottle of BIKTARVY®. Gilead responded by asking Safe Chain why it was inquiring about the product and requesting more information and photographs of the bottle. Safe Chain did not provide photographs or otherwise explain what had prompted the inquiry, but it did send a purported pedigree document for the bottle. The pedigree in question claimed an initial sale of BIKTARVY® from Gilead to a "drug co-op," and then to Defendant Boulevard, and then to Safe Chain. Gilead responded on October 9, 2020 that the transaction history was incorrect, and that the drugs on the pedigree "should be treated as an illegitimate product and quarantined and should be reported to the FDA." Safe Chain did not respond to Gilead's e-mail.
- one in New York City and the other in Washington D.C. about counterfeit bottles of BIKTARVY® and DESCOVY® that the pharmacies had purchased from Safe Chain. The pharmacy in Washington D.C. provided the pedigree for the counterfeit bottle of DESCOVY®, which indicated that Safe Chain had purchased it from Defendant Boulevard. Gilead and its outside lab tested both bottles and confirmed they were counterfeit.
- 155. On March 23, 2021, Gilead, through outside counsel, wrote to Safe Chain's counsel detailing the two new complaints. Gilead demanded that Safe Chain quarantine

all Gilead product in its inventory and provide all documentation, including pedigrees, of all Gilead-branded medication it had purchased since 2020.

- 156. Safe Chain responded on March 26, 2021. Safe Chain refused to quarantine its Gilead product in inventory or to provide documentation for all its purchases of Gilead product. Instead, Safe Chain attempted to blame the counterfeiting on Gentek, and claimed that it had ceased all purchases from Gentek.
- 157. On March 29, 2021, Safe Chain wrote again to disclose that the same day it sent its previous letter, it received a report from a pharmacy customer in Washington D.C. that it had purchased two counterfeit bottles of BIKTARVY®, each with different lot numbers, from Safe Chain. Safe Chain stated it was sending samples of those counterfeits to Gilead, and attached their pedigrees, which showed Safe Chain acquired one of the counterfeits from Boulevard.
- 158. The pedigrees showed that Safe Chain purchased these two counterfeits from Boulevard months *after* Gilead informed Safe Chain that Boulevard was using fake pedigrees to sell illegitimate Gilead medication and instructed Safe Chain to quarantine medication from Boulevard and report it to the FDA. Instead, Safe Chain continued buying from Boulevard and subsequently sold dangerous counterfeits supplied by Boulevard to pharmacies, where they were dispensed to unsuspecting patients, placing the patients' health and lives at risk.

4. Safe Chain's Willful Sales of Counterfeits from Rapid's Tex

159. As alleged above, on March 29, 2021, Safe Chain informed Gilead of two additional counterfeit reports from a pharmacy, one bottle of which Safe Chain purchased from Boulevard. Safe Chain purchased the other counterfeit from a Texas distributor, Mr. Unlimited LLC ("Mr. Unlimited") who in turn had purchased it from another Texas distributor, Defendant Rapid's Tex Wholesales Corp. ("Rapid's Tex").

- 160. Safe Chain's March 29 letter was the first time Gilead learned that Safe Chain was buying counterfeits from Mr. Unlimited and Rapid's Tex. Safe Chain had sold that particular counterfeit to a Washington D.C. pharmacy on March 22, and the pharmacy reported it as counterfeit on March 26. But Safe Chain knew it was buying counterfeits from Mr. Unlimited and Rapid's Tex well before that.
- 161. On or before March 9, 2021, Safe Chain received what it identified as counterfeit bottles of BIKTARVY® from Mr. Unlimited, which had purchased them from Rapid's Tex. Safe Chain never reported those counterfeits to Gilead, nor did it quarantine them as required by the DSCSA. Instead, Safe Chain returned the bottles to Rapid's Tex for a refund. Safe Chain's co-conspirator, Defendant Brosius of Worldwide Pharma, explained in an email:

There are 3 LOTS of Biktarvy from Gilead that have proven to be bad/counterfeit. . . . our legal counsel told us we could not take/receive these lots of Biktarvy. There were 3 units on the prior invoice. Gilead and the California BOP [*i.e.*, Board of Pharmacy] have deemed those 3 lots as 'bad.' We explained to Rapid's Tex and they understood. thanks.

Rapid's Tex responded by announcing "we will be shipping out today another order."

- 162. Receiving counterfeit Gilead medication from Rapid's Tex did not deter Safe Chain and Worldwide Pharma from continuing to buy several hundred more bottles of purported Gilead medication, all with fraudulent pedigrees and at too-good-to-be true pricing, through these entities.
- 163. Rapid's Tex's next shipments contained more counterfeit BIKTARVY® with new lot numbers the confirmed counterfeit BIKTARVY® that Safe Chain reported to Gilead on March 29, plus two more tested and confirmed counterfeits that were reported by a different pharmacy the following month. These confirmed counterfeits are the ones that were

reported to the dispensing pharmacy and to Safe Chain, and which Safe Chain chose to report to Gilead. There are almost certainly many other counterfeits that were never reported to Gilead.

5. Safe Chain Continues Its Counterfeiting, and Attempts Another Blatant Lie to Cover It Up

- 164. As the reports of Safe Chain's sales of counterfeits to pharmacies continued to come in, Safe Chain eventually promised Gilead that it had stopped purchasing from the counterfeit suppliers that Gilead knew about: Gentek, Boulevard, and Mr. Unlimited / Rapid's Tex. But Safe Chain did not agree to stop buying and selling Gilead HIV medications from illegitimate suppliers. Instead, Safe Chain came up with another scheme to cover its tracks and throw off Gilead's investigation.
- 165. On an April 20, 2021 call between Gilead's counsel and Safe Chain's counsel, Safe Chain stated that it had a new source for Gilead products that was buying directly from Cesar Castillo LLC ("Cesar Castillo"), a Gilead authorized distributor. Gilead asked Safe Chain to produce pedigrees for those purchases, but Safe Chain did not do so.
- 166. On May 3, 2021, Gilead served subpoenas on Safe Chain, Boulevard, and Mr. Unlimited as part of an ongoing lawsuit in Florida federal court concerning fraudulent diversion of Gilead HIV medications (the "Florida Action"). The following day, Safe Chain's counsel memorialized in a letter Safe Chain's earlier representation that it now had a legitimate source for Gilead product:

Safe Chain has begun making purchases of Gilead-branded products from a supplier who sourced them from Cesar Castillo (Gilead's authorized distributor). As I mentioned, Safe Chain has contacted Cesar Castillo to verify that this supplier is not only a customer of Cesar Castillo, but also that their account number on file with Cesar Castillo matches the account number that was listed on the Cesar Castillo invoices provided by the supplier to Safe Chain substantiating the supplier's purchase of Gilead products from Cesar Castillo. Safe Chain is willing to provide the list of lot numbers and expiration dates for the products which Safe Chain had purchased from the supplier who sourced them from Cesar Castillo, along

with the T3 reports, **provided Gilead agrees to meet the conditions below**.

(emphasis added). The "conditions" that Safe Chain demanded were untenable. They included "[w]ithdrawal of the Subpoena served on May 3, 2021," and the following:

Please provide an acknowledgement that Safe Chain has not falsified any of the T3 Reports previously provided to Gilead (as had been previously insinuated) and provide a release to Safe Chain regarding its sales of Gilead-branded medications. . . . if [Gilead] would like Safe Chain to continue voluntarily producing additional information to Gilead, it will need this protection in place. This is perhaps the most important requirement."

(emphasis added).

- 167. Gilead, of course, did not agree to falsely "acknowledge" that Safe Chain never falsified a pedigree (in fact, Safe Chain had falsified pedigrees), to withdraw the subpoena, or to give a blanket release of all its legal claims against Safe Chain. And so Safe Chain kept the identity of its new supplier secret.
- customer who had received multiple counterfeits from Safe Chain, provided Gilead copies of its communications with Safe Chain, including pedigrees. Among the documents were four pedigrees for Gilead HIV medications, including BIKTARVY®, that The Medicine Shoppe received from Safe Chain on April 19, 2021. Consistent with Safe Chain's representations to Gilead, the pedigrees did show an initial sale to Cesar Castillo, the authorized Gilead distributor. The pedigree also identified Safe Chain's new mystery supplier: Defendant Synergy Group Wholesalers LLC ("Synergy"). The pedigrees purport to show that Synergy purchased the Gilead HIV medications from Cesar Castillo and immediately sold them to Safe Chain.
- 169. Gilead's subsequent investigation revealed that those pedigrees are fraudulent, and that Safe Chain's claim that it had verified the purchases from Cesar Castillo was a lie. Gilead never sold the lot numbers listed on the pedigrees to Cesar Castillo. Cesar Castillo

has never sold Gilead products (or any other products) to Synergy, has never heard of either Synergy or Safe Chain, and was never contacted by Safe Chain. In fact, Cesar Castillo has never sold a Gilead product to another distributor, period: it sells only to pharmacies and to medical facilities like hospitals and clinics.

- 170. Gilead's investigation has further revealed that Synergy is a sketchy, fly-by-night operation in the same mold as Safe Chain's other counterfeit suppliers. Synergy received its pharmacy distribution license in September 2020, just months before it starting selling to Safe Chain. It is not licensed to sell drugs across state lines to Safe Chain's warehouses, and it is not registered with the FDA. It has no website or Internet presence.
- 171. The Medicine Shoppe's files included an additional pedigree concerning purchases of nearly 100 bottles of Gilead HIV medications, including BIKTARVY®, from Safe Chain in early March 2021. The pedigree states that Synergy purchased the drugs directly from Gilead. That is false. Synergy is not an authorized distributor, and it has never bought directly from Gilead.
- 172. Safe Chain's flagrant lies lying about having a "new" distributor who was purchasing directly from a Gilead authorized distributor, and lying about having directly verified those purchases with the authorized distributor were intended to stymie Gilead's investigation and to conceal Safe Chain's continued purchase and sale of dangerous counterfeit Gilead HIV and other medications.

E. ADDITIONAL EVIDENCE OF SAFE CHAIN'S WILLFULNESS

1. Safe Chain Purchased and Sold the Counterfeits at an Impossible Discount

173. Gilead sells to all its U.S. authorized distributors at a list price known as the wholesale acquisition cost, or WAC. But Safe Chain purchased and sold supposed Gilead medication from its counterfeit suppliers at prices well below WAC – meaning the drugs

somehow became less expensive *after* Gilead sold them and they passed through various distributors' hands.

174. In fact, Safe Chain and Worldwide Pharma actively advertised to pharmacies that their sales prices were below WAC. Safe Chain and Worldwide Pharma knew that was an impossible discount for authentic, legitimately sold Gilead medication.

2. Safe Chain Purchased Gilead Medication with Obviously Fake Pedigrees

175. The pedigrees that Safe Chain received from its counterfeit suppliers were riddled with errors and anomalies, including stating the same drug was delivered to multiple recipients in different states, all on the same day; indicating that a drug was sold before the upstream distributor even received it; and leaving multiple required fields on the pedigrees blank. At minimum, these errors and inconsistencies were suspect, triggering Safe Chain's obligation under the DSCSA to conduct an investigation. Instead, Safe Chain sold the counterfeits to pharmacies.

3. Safe Chain Knew It Was Buying from Fly-by-Night, Unlicensed, and Unauthorized Counterfeit Suppliers

176. All of Safe Chain's known counterfeit suppliers – Gentek, Boulevard, Rapid's Tex, and Synergy – are shady, fly-by-night counterfeiters who only recently opened their doors and lacked proper licensure and registration to sell prescription drugs across state lines. None of them has a website or an Internet presence. None of them are "authorized" suppliers under the DSCSA, and none of them can lawfully sell prescription medications.

177. None of the four counterfeit suppliers is registered with the FDA or has met its annual reporting requirements to the FDA. Moreover, none of them is licensed to sell pharmaceuticals in Utah or Maryland, where they shipped the counterfeit drugs to Safe Chain.

- 178. Checking to see whether a distributor is properly licensed and registered can be done by entering the distributor's name into the FDA's public online national database of pharmaceutical distributors, which takes seconds.
- 179. Every time Safe Chain sold a drug that it purchased from one of these counterfeit suppliers, Safe Chain affirmatively certified on its pedigree that it "received the product from a person that is authorized as required under the Drug Supply Chain Security Act." Every one of those certifications was knowingly false. Safe Chain communicated with Defendant Adam Brosius about the counterfeit nature of Defendant Synergy's inventory of purported Gilead medications, and strategized with him about how to obtain counterfeit medications from Defendant Boulevard.

a. Boulevard

- 180. Defendant Boulevard is not licensed as a pharmaceutical distributor.

 Boulevard is licensed as a retail pharmacy. All of its sales of prescription drugs to an out-of-state distributor like Safe Chain are illegitimate on their face.
- 181. Boulevard's owner and principal, Defendant Shukurov, owns another pharmacy that is involved in a massive prescription drug fraud scheme that is the subject of a federal prosecution, and Shukurov is an unindicted co-conspirator in that scheme.
- 182. After its counterfeiting came to light, Boulevard abandoned its small offices in a condominium building in Queens and stopped answering its phones.

b. Gentek

- 183. Defendant Gentek was run out of its principal's home on a lot zoned for residential use in Stamford, Connecticut.
- 184. When a pharmacy reported to Safe Chain that it had sold the pharmacy a counterfeit bottle of Gilead HIV medication with a foreign drug inside one of its counterfeits,

Defendant Charles Boyd, Safe Chain's co-founder and CEO, emailed Gentek's principal to ask for a refund. Charles Boyd emphasized that he was seeking a refund only for "this one bottle." The supplier's response email was as follows, with the all-caps and punctuation errors in the original:

GOOD MORNING

WILL CREDIT SAFE CHAIN FOR THE PRODUCT. PLEASE GO AHEAD AND DESTROY THE PRODUCT .THATS A MIXED BATCH ERROR ON OUR AD.

SORRY FOR ANY INCONVENIENCE.

Edel Reyes PESIDENT

The abbreviation "AD" stands for "authorized distributor." The typo "PESIDENT" appears in the signature block of every email Gentek sent to Safe Chain.

185. That was the entirety of the "explanation" Safe Chain's supplier provided for the counterfeit Gilead HIV medication. That "explanation" was nonsensical and betrayed Gentek's startling misunderstanding of how pharmaceutical distribution works. Gilead sells to its authorized distributors filled, sealed, ready-to-dispense bottles of Gilead medication. Authorized distributors do not open or repackage those bottles. To claim that a counterfeit bottle containing the wrong medication is the result of an authorized distributor's "mixed batch error" is an obvious and deeply concerning misrepresentation.

186. Despite knowing that Gentek's explanation was clearly false, Safe Chain did not object. Instead, Charles Boyd of Safe Chain wrote back cheerily to inquire about his refund: "Thanks! Please let me know how you would like to handle the credit."

c. Rapid's Tex

- 187. In order to facilitate its purchase of counterfeits from Defendant Rapid's Tex, Safe Chain and Worldwide Pharma conspired to identify and bribe what they called a "pass-through" wholesaler: Mr. Unlimited.
- 188. Unlike Rapid's Tex, Mr. Unlimited is an "authorized" distributor under the DSCSA: it has been licensed in Texas as a drug distributor since 2009, maintains a current registration and files annual reports with the FDA, and has an out-of-state pharmaceutical distributor's license in Utah. Under the pass-through scam, Rapid's Tex nominally sold to Mr. Unlimited, who immediately forwarded the supposed Gilead medications to Safe Chain. Rapid's Tex and Mr. Unlimited then papered the "pass-through" transaction by creating, after the fact, invoices, purchase orders, and pedigrees claiming that Mr. Unlimited purchased from Rapid's Tex and sold to Safe Chain.
- 189. The purpose of the pass-through scam was to use Mr. Unlimited's licensure to "whitewash" the pedigrees. It allowed Safe Chain to claim it was buying directly from a legitimate supplier (Mr. Unlimited) when in fact it was sourcing fake Gilead medications from the unlicensed, fly-by-night counterfeiter Rapid's Tex. For its participation in the scheme, Mr. Unlimited was paid an up to \$1500 kickback per order. Safe Chain listed that kickback as a separate line item on its purchase orders as "PASS THROUGH FEE."
- 190. Safe Chain's upper management orchestrated the pass-through scam with Brosius and Worldwide Pharma. Safe Chain, Worldwide Pharma, Mr. Unlimited, and Rapid's Tex are all on numerous emails concerning the pass-through scam. When complications arose with the scam, Mr. Unlimited told a Safe Chain employee that he "spoke with Safe Chain's owner," and instructed Safe Chain's representative to get the details from Worldwide Pharma.

- 191. Safe Chain's "pass through" scam had one shortcoming: the pedigrees it received from Mr. Unlimited still listed the unlicensed counterfeiter Rapid's Tex as an upstream supplier. When the patient complaints continued to roll in and Gilead's investigation intensified, Safe Chain began to create new fraudulent pedigrees that simply erased Rapid's Tex from the chain of sale completely. For example, in March 2021 Safe Chain sold several dozen bottles of BIKTARVY® to The Medicine Shoppe. As with several other orders, Safe Chain had ordered those bottles directly from Rapid's Tex and caused it to be "passed through" Mr. Unlimited. And yet Safe Chain's pedigree for the sale to The Medicine Shoppe fraudulently indicated that Gilead had sold the drugs directly to Mr. Unlimited, with no mention of Rapid's Tex whatsoever.
- 192. All of the pedigrees that Mr. Unlimited generated for Safe Chain as part of the pass-through scam stated that Mr. Unlimited received the drugs from Rapid's Tex. The fraudulent pedigrees claiming that Gilead sold directly to Mr. Unlimited were created by Safe Chain itself, out of whole cloth.

4. Worldwide Pharma's Willful Counterfeiting

- 193. Worldwide Pharma advertises itself as a marketing "sales engine" that connects pharmaceutical distributors with independent pharmacies. Worldwide Pharma is founded, owned, and operated by Brosius, who at all relevant times was and remains under federal indictment for health care fraud. Worldwide Pharma and Brosius conspired with Safe Chain to traffic the counterfeits. Worldwide Pharma and Brosius both worked directly with counterfeit suppliers and with unwitting customers, as well as operated behind the scenes to coordinate and assist Safe Chain in its willful purchase and sale of counterfeit Gilead HIV and other medications.
- 194. Worldwide Pharma and Brosius were copied on Safe Chain's purchases of counterfeit Gilead HIV and other medications from Safe Chain's counterfeit suppliers.

Worldwide Pharma and Brosius marketed Safe Chain's products – which, unbeknownst to the customers, were counterfeits – to pharmacies, and convinced pharmacies to buy the counterfeits from Safe Chain. Worldwide Pharma and Brosius also interfaced directly with pharmacies during the purchasing process, sending Safe Chain's invoices and pedigrees directly to pharmacy customers, including pharmacy customers located in New York.

195. Brosius was previously the chairman of the board of an independent pharmacy, and was tasked with bringing the pharmacy into compliance with federal law and regulations. Instead, Brosius used his position to run a vast, \$35-million health care fraud scheme through the pharmacy.

fake "test" claims to various insurers in order to pinpoint which precise ingredients in particular compounded medications would result in the largest insurance payoff for the pharmacy. Brosius then created preprinted prescription pads that listed a handful of high-value compound medications that could be prescribed by checking a box. Brosius then caused a company he owned, Pharma Sales Group, Inc. (a predecessor to Worldwide Pharma) to hire marketers to recruit physicians who used virtual or remote-consultation platforms. These physicians used Brosius's check-box prescription pads to prescribe unnecessary medications to patients, many of whom they never examined, and then sent the prescriptions to Brosius's pharmacy to get filled. To prevent patients from objecting or returning the medication, Brosius caused the pharmacy to waive the patients' co-insurance, and caused money orders to be forged in the amount of the co-pays submitted to the pharmacy. Brosius caused the pharmacy to pay a percentage of the insurance reimbursements to his wholly owned company.

- 197. Brosius was indicted on four counts of health care fraud and conspiracy to commit health care fraud, and payment of kickbacks in connection with a federal health care program, and conspiracy to violate the anti-kickback statute on or about July 10, 2020.
- 198. Prior to the indictments, Brosius's pharmacy hired external counsel to conduct an internal investigation, which ended with Brosius being instructed to resign from the board. Immediately after being drummed out of his pharmacy, Brosius founded Worldwide Pharma. Brosius is listed as the company's registered agent and president on the corporate registration, and lists the company's business purpose as "consulting services for pharmaceutical dispensing."

5. The Boulevard Defendants' Willful Counterfeiting

- 199. Boulevard sold multiple confirmed counterfeits to Safe Chain, and many additional bottles of Gilead HIV medications with fraudulent pedigrees that listed initial sales from Gilead that did not occur. Boulevard of course knew that it had not purchased the counterfeits from the legitimate sources it fraudulently listed on the fake pedigrees.
- 200. On May 3, 2020, Gilead served Boulevard with a federal subpoena in connection with an ongoing litigation in the Southern District of Florida that involves illegally diverted bottles of Gilead HIV medications with false pedigrees, including large quantities of medication purchased back from patients. Boulevard was duly served and received the subpoena, but chose not to respond in any way.

F. THE JULY 26, 2021 SEIZURE

201. On July 23, 2021, this Court issued an *ex parte* seizure order permitting seizures at Safe Chain's headquarters and satellite distribution center, and, with Boulevard having abandoned its offices, at the residence of Shukurov.

- 202. At the seizure at the two Safe Chain locations, Gilead recovered over a thousand bottles of purported Gilead product from Safe Chain's shelves. While Gilead's review of the products and documentation seized is ongoing as of the date of this filing, Gilead has confirmed that in addition to counterfeit bottles of BIKTARVY® and DESCOVY®, Gilead seized from Safe Chain counterfeits of seven additional Gilead medications: TRUVADA®, GENVOYA®, ATRIPLA®, SOVALDI®, STRIBILD®, VOSEVI®, and RANEXA®.
- 203. The purported Gilead medication seized from Safe Chain showed obvious signs of tampering. Some of the bottles had obviously fake caps:



204. A large number of purported Gilead bottles seized from Safe Chain were missing the FDA-mandated Instructions for Use that are affixed to the outside of every authentic bottle (often referred to as the "outsert"). Many other purported Gilead bottles showed clear signs that Instructions for Use had been re-glued to the bottles – and often the wrong Instructions for Use. Some of the Instructions for Use attached to the bottles of purported Gilead medication were counterfeits printed by the counterfeiters, identifiable by, among other things, spelling errors in the documents.

- 205. The pedigrees for the purported Gilead product in Safe Chain's inventory were fake and fraudulent.
- 206. At the seizure at his residence, Shukurov confirmed that he was the owner and principal of Boulevard on paper, but stated that a man paid him \$5,000 a month to "sign some papers" and open businesses in Shukurov's name, including Boulevard. Shukurov claimed to have no other involvement in Boulevard's business. Shukurov identified Abdullaev as the individual who paid him to sign the papers founding Boulevard, and Gilead seized a notebook in which Shukurov had recorded Abdullaev's name, phone number, and license plate number. Bank records collected during the seizure and in subsequent discovery confirmed that Shukurov received regular payments of \$5,000 or \$10,000 from Boulevard. The bank records showed that Shukurov signed all of Boulevard's checks, including payments to pharmacies and distributors, as well as Boulevard's payments to Shukurov himself.

1. Khaim's and Abdullaev's Willful Counterfeiting

- 207. Records that Gilead recovered during the July 26, 2021 seizure show that Khaim was Boulevard's primary point of contact with Safe Chain including in connection with Boulevard's sale and delivery of counterfeit Gilead medications with fake pedigrees. Khaim directly communicated about the counterfeits with, for example, Charles Boyd and Brosius. Khaim's name was saved in Charles Boyd's phone as "Peter Boulevard."
- 208. Khaim and his brother, Arkaidy Khaimov, are currently under indictment for running a multi-million-dollar pharmaceutical fraud scheme. The indictment states that the Khaim brothers bribed the nominal owners of several pharmacies including one nominally owned by Shukurov to allow them to use those pharmacies to fill fake prescriptions for expensive cancer-related medication. Khaim and his brother then pushed those fake

prescriptions through for insurance reimbursement by using emergency override procedures established for the COVID-19 pandemic.

- 209. Khaim's sale of counterfeit HIV medication through Boulevard, again using Shukorov as a false proxy, is a similarly structured scheme but this time, Khaim put the lives of countless HIV patients at risk with fake drugs.
- 210. Khaim was indicted on December 18, 2020. Safe Chain was aware of, and discussed a press release concerning, Khaim's indictment no later than January 2021. And yet Khaim continued to sell, and Safe Chain continued to buy, counterfeit Gilead medication in at least February and March 2021.
- 211. Khaim arranged for the purported Gilead drugs to be hand-delivered to Safe Chain by his "driver." Khaim emphasized to Charles Boyd that these hand deliveries were "the best way" to send the counterfeits. Below is a picture from Safe Chain's files of a delivery of purported Gilead product that Khaim had hand-delivered to Safe Chain on behalf of Boulevard:



- 212. Brosius wrote to Charles Boyd that this jumbled mess of obviously illegitimate product was "silly" but Safe Chain and Worldwide Pharma continued to buy millions of dollars' worth of purported Gilead medication from Khaim and Boulevard.
- 213. Safe Chain's communications with Khaim and Boulevard make clear that Safe Chain knew Boulevard was providing fake pedigrees for Gilead products. At one point, Safe Chain asked if Boulevard had invoices or upstream pedigrees proving that the drugs came from the sources listed on Boulevard's pedigrees. Using a generic gmail email address, Boulevard offered instead only vague empty assurances: "No I do not. But it's 100 percent np [i.e., no problem]. You Il have no problems its all accurate."
- 214. In several instances, Safe Chain purchased medication from Boulevard, and then sold that medication to pharmacies, without having received any pedigrees from Boulevard at all. For example, in August 2020 Brosius wrote to Charles Boyd and others that pharmacies were demanding the missing pedigrees, but Boulevard was unwilling to provide them until Safe Chain paid its outstanding debt of over \$1 million. Brosius concluded his email by writing, "HELP!" Charles Boyd responded that he had spoken with Khaim and come up with a solution to the problem.
- 215. Abdullaev bribed Shukurov to open Boulevard in Shukurov's name in order to conceal Abdullaev's and Khaim's involvement in Boulevard's criminal counterfeiting. Abdullaev is currently residing in a house owned by a limited-liability corporation that is owned by members of the Khaim / Khaimov family, and is currently deeded to Arkadiy Khaimov, Defendant Peter Khaim's brother and his co-defendant in the pending pharmaceutical fraud criminal action.

2. Synergy's Willful Counterfeiting

216. Documents obtained from the Safe Chain seizure show that Synergy engaged in an elaborate ruse in connection with its sale of Gilead products.

217. As alleged above, in May 2021, Safe Chain claimed it had a new supplier for Gilead products which purchased Gilead-branded medicines directly from Cesar Castillo LLC, a Gilead authorized distributor. Safe Chain further claimed it had verified this to be true directly with Cesar Castillo, including by verifying its new supplier's account number with Cesar Castillo. Safe Chain refused to disclose the identity of this new supplier unless Gilead met certain unreasonable "conditions," but Gilead's investigation identified the new supplier as Synergy.

218. Emails seized from Safe Chain show that in April 2020, Patrick Boyd of Safe Chain wrote to Defendant Vega of Synergy, asking for written confirmation that Synergy had purchased Gilead products from Cesar Castillo. In response, Vega forwarded Boyd's email to one "Bary Sanchez" at the email "bary.sanchez@cesarcastilloinc.co" requesting this verification. "Mr. Sanchez" replied with the below email:

From: Bary Sanchez <bary.sanchez@cesarcastilloinc.co>

Sent: Tuesday, April 20, 2021 5:00 PM

To: Carlos Vega <carlos@synergygroupwholesaler.com>; Pat Boyd <PatB@Safechain.com>

Subject: Re: Invoice and T3 discrepancies to correct

Hi Carlos / Pat

Acct number is 585720797.

Bary Sanchez Account Executive Cesar Castillo Inc

Carr. #1 Km 21.1 Sector La Muda

Guaynabo, PR 00971 Direct: 787-247-1527

Email: Bary.Sanchez@CesarCastilloInc.co

- 219. The above email is a sham. The signature block shows the name and address of a real Cesar Castillo employee. The email address, however, is a spoof. Cesar Castillo's website is www.cesarcastillo.com, and its employees have @cesarcastillo.com email addresses. The fraudulent email above uses a @cesarcastilloinc.co email address.
- 220. According to public records, that sham domain name was registered just a week before the fraudulent "Cesar Castillo" email above was sent:

Domain Name: cesarcastilloinc.co
Registry Domain ID: D024076EEAFD5420A951CB98F5A7E4531-NSR
Registrar WHOIS Server: whois.domain.com
Registrar URL: www.domain.com
Updated Date: 2021-04-13T01:53:13Z
Creation Date: 2021-04-13T01:53:11Z
Registry Expiry Date: 2022-04-13T01:53:11Z
Registrar: Domain.com, LLC
Registrar IANA ID: 886

- 221. Shortly before the fraudulent "Cesar Castillo" email was sent, Safe Chain's Director of Compliance had emailed Safe Chain's co-owners Charles and Patrick Boyd noting that Synergy was using a fake email address for a purported contact at Cesar Castillo, Bary Sanchez, on its pedigrees: "this email is incorrect, from the company webpage their emails end with 'cesarcastillo.com' not the 'cesarcastilloinc.com' as listed on the Pedigree." She also included a link to www.cesarcastillo.com to show that was the distributors' actual website.
- 222. Patrick Boyd privately responded to Charles Boyd by saying of the Director of Compliance that "[s]he has ever [sic] reason to be skeptical," but that she needed to tone down her language.
- 223. When the "Cesar Castillo" email from "Mr. Sanchez" came in a couple of weeks later, Patrick Boyd immediately responded, "Thanks for your help with this Bary."
- 224. This was not the first time Synergy had used a fake supplier email address to pretend it purchased from a legitimate source. Several weeks earlier, on March 3, 2021, Safe

Chain's compliance specialist had reached out to an upstream distributor concerning a non-Gilead product Safe Chain had purchased from Synergy. Safe Chain's compliance specialist noted that Synergy's pedigree had listed facially false contact information for the upstream distributor: "The contact Jefferey Anderson, his phone was in different area code then [sic] where you are located and he is using a Gmail account instead of a company account."

- 225. The distributor confirmed to Safe Chain that Synergy's pedigree was fraudulent: "These products were not purchased from us. We did employ someone named Jeffrey Anderson however he is no longer with the company. We have no existing relationship with Synergy Group Wholesalers so any Transaction History that they give you with our information is incorrect. We appreciate you bringing this to our attention and will submit a report with the FDA." Safe Chain's compliance director immediately forwarded that response to Defendant Patrick Boyd, who in turn forwarded it to Defendant Adam Brosius with the following note: "potential problem." But Safe Chain continued to purchase purported Gilead products from Synergy, knowing full well Synergy's business was illicit.
- 226. All of the pedigrees for all of the Gilead-branded medications that Synergy sold to Safe Chain are falsified and fraudulent.

3. ProPharma's Willful Counterfeiting

- 227. In July 2021, Gilead learned from a pharmacy that ProPharma had sold a potentially dangerous counterfeit bottle of BIKTARVY®, which contained the wrong drug.
- 228. The pharmacy discovered the counterfeit because the patient, who had taken BIKTARVY® for years, felt ill after ingesting the counterfeit, and reported it to his physician. Gilead retrieved and tested the bottle and confirmed it to be counterfeit.
- 229. The reporting pharmacy provided the pedigree for the counterfeit, which indicated that ProPharma had purchased the counterfeit from a distributor named Defendant

Omom Pharmaceuticals, Inc. ("Omom"), which claimed to have purchased it from a Gilead authorized distributor. That pedigree was fake: the claimed initial sale from Gilead to the authorized distributor never occurred.

- 230. The reporting pharmacy also provided Gilead with dozens of additional pedigrees for purported Gilead products it had purchased from ProPharma. Those pedigrees were also fake and listed transactions that had never occurred. The vast majority of the pedigrees indicated that ProPharma purchased the purported Gilead drugs from Omom.
- 231. Separately, two pharmacies and a pharmacy trade association contacted Gilead to report that they had received fake pedigrees for Gilead medications from ProPharma. Most of those pedigrees indicated the drugs had come from Omom.
- 232. For each and every sale of purported Gilead product that it purchased from Omom, ProPharma knowingly lied on the pedigrees it sent to its customers by falsely certifying that it purchased the drugs from an "authorized" trading partner under the DSCSA.
- 233. Although Omom has licensure in North Carolina, and ProPharma has a distribution center in North Carolina, pedigrees show that Omom unlawfully delivered counterfeit medications to ProPharma in Colorado, where Omom does not have licensure to sell across state lines.
- 234. Safe Chain has also purchased purported Gilead products from Omom. Safe Chain orchestrated a "pass-through" scam for its purchases from Omom. Although Safe Chain's internal records reflect that it purchased the counterfeits directly from Omom, Safe Chain recruited and bribed a properly licensed distributor to make straw "purchases" from Omom and then immediately "sell" those medications to Safe Chain. This allowed Safe Chain to

pretend it was purchasing Gilead products from a legitimate source when in fact it was sourcing counterfeits directly from the unlicensed counterfeiter.

- 235. Safe Chain's "pass-through" distributor for its purchases from Omom was Professional Medical Warehouse ("PMW"). ProPharma also used PMW as a pass-through for some of its purchases from Omom.
- 236. Shortly after the July 26, 2021 seizure at Safe Chain's premises, Omom abandoned its offices. Omom's principals used fake names when corresponding with Safe Chain, and as a result, Gilead's investigators have been unable to locate Omom or its principals.
- 237. As alleged below, Gilead conducted a seizure of ProPharma's premises on August 26, 2021. At the seizure, Gilead seized over 17,000 bottles of purported Gilead-branded HIV medication. All of the bottles had counterfeit pedigrees and many had counterfeit outserts.

4. The Pharmacy Defendants' Willful Counterfeiting

- 238. Each of the Pharmacy Defendants purchased over ninety-five bottles (and in some cases, hundreds) of purported Gilead medication, all of them with fake pedigrees, from Safe Chain.
- 239. Each of the Pharmacy Defendants received pedigrees from Safe Chain for purported Gilead medication that were manifestly falsified because, among other things, they listed an initial sale from Gilead not to an authorized distributor, but rather to a fly-by-night counterfeiter.
- 240. Despite knowing these pedigrees to be false, the Pharmacy Defendants continued to buy counterfeits from Safe Chain.
- 241. Gilead warned each of the Pharmacy Defendants in writing that Safe Chain was selling counterfeit Gilead-branded products with falsified pedigrees. Despite that warning, the Pharmacy Defendants continued buying counterfeits from Safe Chain.

- 242. After executing the Seizure Order at Safe Chain's premises, Gilead sent warning letters and served subpoenas to Safe Chain's pharmacy customers, including the Pharmacy Defendants. The Pharmacy Defendants ignored this warning as well, and ignored Gilead's duly served subpoenas.
- 243. Each of the Pharmacy Defendants' purchase and sale of counterfeit Gilead products with fake pedigrees was knowing and willful, or, at minimum and in the alternative, willfully blind.

G. THE AUGUST 23, 2021 SEIZURES

244. On August 20, 2021, this Court issued an *ex parte* seizure order permitting seizures at Pro Pharma's headquarters and satellite distribution center, at the residences of Boulevard principals Khaim and Abdullaev, and at the residence of Synergy principal Vega. The seizures were conducted on August 23, 2021. Thousands of bottles of counterfeit Gilead HIV medications, with falsified pedigree and counterfeit outserts, were seized from the ProPharma Defendants. Records of ProPharma's trafficking in counterfeits were also seized. Records of Boulevard and Synergy counterfeit trafficking were seized at the residences of the Boulevard principals and Vega, respectively. However, Khaim and Vega concealed evidence and refused to cooperate with the seizure order.

H. DEFENDANTS' COUNTERFEITING RING

245. Seized documents and information obtained through third-party discovery have revealed that the known suppliers and distributors of counterfeit Gilead HIV medication are not the disparate actors they appeared to be. Rather, the counterfeits are being sold through an organized counterfeiting ring: a large-scale, transnational enterprise comprised of numerous individual and entities working in concert to sell counterfeit Gilead-branded HIV medications into the United States supply chain. The evidence shows that this counterfeiting ring is

organized and orchestrated by three ringleaders: Defendants Ralhan, Rosell, and Mannava, the "Leader Defendants."²

- 246. The Leader Defendants move the counterfeits through the various fly-bynight (and ultimately expendable) corporations referred to as the "Supplier Defendants." But
 most pharmacies are reluctant to buy directly from shady, newly formed, sometimes unlicensed
 suppliers such as the Supplier Defendants. For this reason, the counterfeiting ring needs to work
 through pharmaceutical distributors (the "Distributor Defendants"), who have the licensure and
 the established business presence to attract pharmacy customers. To lure in the pharmacies, the
 Leader Defendants brought in their own dedicated sales force, the "Marketer Defendants," to
 advertise the counterfeits to pharmacies and generate sales.
- 247. The Leader Defendants introduce the Supplier Defendants to the Distributor Defendants; the Supplier Defendants sell the counterfeits to Distributor Defendants; the Distributor Defendants sell the counterfeits to the pharmacy customers drummed up by the Marketer Defendants; and the Leader Defendants collect a large cut of the profits (and share it with the Marketer Defendants). The proceeds of the operation are concealed and laundered by being moved through various shell entities (the "Asset Holder Defendants") organized and controlled by the Leader Defendants and/or the Supplier Defendants. All these Defendants knowingly work in concert to sell counterfeits, falsify business records, and launder money.
 - 1. The Leader Defendants (Ralhan, Rosell, And Mannava) Orchestrate the Purchasing, Sale, and Advertising of the Counterfeits
- 248. The Leader Defendants, Ralhan, Rosell, and Mannava, are responsible for pushing tens of thousands of bottles of counterfeit Gilead-branded medications with fake

² A list of the Defendants and the Defendant Groups by which they are referred is attached hereto as Appendix A.

pedigrees through the U.S. pharmaceutical distribution chain. These three individuals organized and managed a host of disparate fly-by-night counterfeiters, including at a minimum Supplier Defendants Gentek, Omom, Invicta, and Pharma Pac, and, as discovery will show, the other Supplier Defendants as well.

249. The Leader Defendants negotiated the pricing and sale of those fly-bynight wholesalers' counterfeit Gilead-branded medications to at least four licensed gray-market
distributors: Distributor Defendants Safe Chain and ProPharma, and newly added Defendants
Scripts and PrimeRx. After establishing these counterfeit pipelines to the licensed distributors,
the Leader Defendants went on to organize the advertising and sale of those counterfeits to
pharmacies, supervising a sales force and sometimes directly selling to pharmacies on the
distributors' behalf.

a. Druhv Ralhan and His Shell Company, D&K Healthcare

- 250. When Safe Chain first entered the business of buying and selling purported Gilead HIV medication in May 2020, it did so through Defendant Druhv Ralhan (who sometimes went by "Drew"). Ralhan first connected Safe Chain with the fly-by-night counterfeiter Boulevard, and over the course of weeks quickly built up Safe Chain's brand-new HIV business to include various purported Gilead-branded medications. Ralhan managed Safe Chain's relationship with Boulevard, relaying orders and occasionally making direct use of Boulevard 9229 LLC's sales email address, 9229sales@gmail.com. The purported Gilead-branded medications that Ralhan marketed and sold were counterfeit and were accompanied by false pedigrees that misrepresented the origin and chain of custody of the medications.
- 251. In the ensuing months, Ralhan introduced Safe Chain to new fly-by-night sources of counterfeit Gilead medication: at minimum, Supplier Defendants Gentek and Omom.

 Ralhan once again and directly negotiated the pricing of the purported Gilead HIV medications

that Safe Chain purchased from those counterfeiters. Ralhan also handled issues with Safe Chain's pricing and payments for purported Gilead products sold by the Supplier Defendants.

- 252. Ralhan also conspired with Distributer Defendant ProPharma. He was introduced to Alex Reyes, a ProPharma employee, in early 2021 by his co-ringleader, Defendant Paul Rosell. In his phone, Reyes saved Ralhan's name as "Dhruv (HIV MEDS)." Ralhan had Reyes sign a non-disclosure agreement ("NDA") prior to their discussion of ProPharma's potential sale of Gilead HIV medication through Ralhan and his colleagues. Ralhan signed that non-disclosure agreement on behalf of Defendant D&K Healthcare, a shell company that he wholly owns. In email correspondence, Ralhan explained that "we" meaning at minimum himself and Rosell "have our own custom software that produces our Pedigree," and discussed "executing a contract with the" distributors who would be providing the HIV medication. Ralhan specified that the "contract will be from my 'broker' side."
- 253. After the deal was struck with ProPharma and Ralhan had established the pipeline for counterfeit HIV medications to ProPharma, Ralhan supervised and resolved disputes among the sales force that was selling the counterfeits to pharmacies on ProPharma's behalf. He also submitted some orders directly. The Gilead-branded medications that Ralhan marketed were counterfeits, bearing falsified pedigrees, falsified instructions for use, and in some cases, containing fake pills.

b. Paul Rosell and His Shell Company, Med-Connect

254. In October 2020, Rosell recruited Distributor Defendant ProPharma into the counterfeiting operation that he and the other Leader Defendants led. Rosell disclosed that he was already selling huge volumes of purported Gilead medication (i.e., the counterfeits) through ProPharma's "two major competitors: Safechain and Scripps [sic]. Safechain is moving about \$5M a week and Scripps [sic] is around \$8M a week." Rosell's proposal to ProPharma

was that his team would handle both the sourcing of the product – initially, through Supplier

Defendant Gentek – and the sales to ProPharma's customers. All ProPharma had to do was
wait for Rosell's team to generate orders from pharmacies, and then ship the counterfeits and
collect payment. As Rosell emphasized in his pitch: "Propharma does not have to provide a
sales force." One of ProPharma's board members responded, "Sounds like a great opportunity to
expand and grow with the help of established relationships from Paul and his people."

- 255. Pursuant to Rosell's plan, ProPharma began purchasing counterfeit Gilead medication from Distributor Defendant Omom in February 2021. In April 2021, Reyes announced that ProPharma's kickbacks from the sales of the counterfeits would now be made "to Paul [Rosell]'s company," Med-Connect. Reyes explained that ProPharma would pay Med-Connect, and then Rosell "will be in charge of disbursements to the teams." Reyes said Rosell's company was the preferred entity to receive payments because "Paul seems to know both sides."
- 256. Pursuant to Rosell's plan, ProPharma trafficked more than 17,000 bottles of purported Gilead-branded HIV medication to U.S. pharmacies. These medications were counterfeits, bearing falsified pedigrees, falsified instructions for use, and in some cases, containing fake pills.
 - c. Venkata Srinivas Mannava and his Shell Company, DSP Consulting, Inc.
- 257. As with his co-Leader Defendants, Mannava's primary role in the conspiracy was to introduce and manage the relationships between the fly-by-night Supplier Defendants and the Distributor Defendants. Mannava is a former pharmacist and a convicted pharmaceutical fraudster who lost his pharmacist's license and was barred from participating in federal healthcare plans after being convicted for participating in a criminal scheme to fraudulently bill insurance for "expensive HIV and cancer medication" that were neither

requested by patients nor actually dispensed. Mannava was also convicted of forging prescriptions for oxycodone, the narcotic at the center of America's opioid addiction epidemic.

- 258. As one of the ringleaders of the counterfeiting scheme, Mannava used the pseudonyms "Srini K." and "Vas Manna," both of which incorporate elements of his full name: Venkata Srinivas Mannava. Through a combination of public-records searches and documents obtained from the ProPharma seizure, Gilead's investigators were able to definitively identify both of these alternate personas as, in fact, Mannava.
- 259. Using his "Srini K" persona, Mannava interfaced directly with ProPharma to set up Defendant Pharma Pac, yet another counterfeit Supplier Defendant, as a ProPharma vendor. Mannava also actively managed ProPharma's relationship with at least three counterfeit suppliers Omom, Invicta, and PharmaPac addressing issues such as payments, missing invoices, maintaining a steady supply, and pricing.
- 260. Mannava also used a shell company he founded in March 2021, Defendant DSP, to receive funds for the counterfeits and distribute kickbacks to his co-conspirators. DSP received kickback payments directly from the counterfeit suppliers as well.
- 261. Mannava also worked on the sales side of the counterfeiting operation. Using his "Vas Manna" persona (often shortened to "Vas M"), Mannava worked directly as a sales representative, using a ProPharma email address and selling purported HIV medication directly to pharmacies. As "Vas Manna," Mannava also worked directly with co-ringleader Ralhan to add new retail pharmacies to the stable of customers for the counterfeits.
 - 2. The Marketer Defendants: Defendants Zangari, Massana, Panagiotopoulos, And Streamlinerx Sell The Counterfeits On Behalf Of The Distributor Defendants
- 262. The Leader Defendants not only provided the Distributor Defendants access to a stable of counterfeit suppliers, but they also provided the sales force to sell those

counterfeits to pharmacies. The heads of the sales force were referred to as "the Canadian Boys": Defendants Mike Zangari, Riccardo Massana, and John Panagiotopoulos, all of whom live in Canada (together, the "Marketer Defendants"). The Marketer Defendants were responsible for managing the sales force that advertised and sold counterfeits to pharmacies on behalf of, at minimum, Distributor Defendants Safe Chain, ProPharma, and Scripts. The Marketer Defendants were organized and operated under the direction of the Leader Defendants.

- 263. In February 2021, when ProPharma first joined the counterfeiting scheme, all three of the Marketer Defendants were on an initial kick-off call with Leader Defendants Ralhan and Rosell, as well as a follow-up email chain with the subject line "ProPharma HIV introduction." All three of the Marketer Defendants managed ProPharma's sales of the counterfeits by receiving emails through the distribution group RXorders@propharmausa.com. Each of the Marketer Defendants sold purported Gilead products to pharmacies on ProPharma's behalf. These medications were counterfeits, bearing falsified pedigrees, falsified instructions for use, and in some cases, containing fake pills.
- 264. Defendants Zangari and Panagiotopoulos were also responsible for selling counterfeits on behalf of Safe Chain. Along with Leader Defendant Ralhan, Zangari and Panagiotopoulos shared an email address, brands@pharmasales.com, through which they submitted pharmacy orders to Safe Chain. Zangari, Panagiotopoulos, and Ralhan split the kickback for Safe Chain's sales of counterfeits among the three of them.
- 265. The Marketer Defendants utilized a shell company, Defendant

 StreamlineRx, in connection with their counterfeit sales. StreamlineRx was formed in February

 2020, and according to its corporate filings its principal is Defendant Pavan Matripragada.

 StreamlineRx's website was registered by D&K Healthcare, the shell company owned by Leader

Defendant Ralhan. Streamline advertises itself as a reimbursement manager for pharmacies that boasts it has "proprietary billing methods" that allow pharmacies to "circumvent PBMs" – i.e., the Pharmacy Benefit Managers that set reimbursement rates for insurance plans. Defendants Zangari and Ralhan submitted invoices to Safe Chain and requested payment for purported Gilead products through StreamlineRx, using an @streamlinerx.net email address.

- 3. The Supplier Defendants: Fly-By-Night Counterfeiters Who Partnered With The Ringleader Defendants To Sell To The Distributor Defendants
- 266. Through the seizures it has conducted to date, Gilead has identified multiple different fly-by-night counterfeit suppliers who sold purported Gilead medications with fake pedigrees, falsified instructions for use, and in some cases, fake pills: Supplier Defendants Boulevard, Synergy, Gentek, Omom, Rapid's Tex, Invicta, and PharmaPac. All of these Supplier Defendants sold large quantities of purported Gilead products with fake pedigrees to the Distributor Defendants. Documents seized from Safe Chain and ProPharma demonstrate that Gentek, Omom, Invicta, and PharmaPac were part of the counterfeiting ring organized by the Leader Defendants.
- 267. Evidence indicates, and discovery will confirm, that all of the Supplier Defendants were part of the counterfeiting ring. Each of the Supplier Defendants followed a distinct pattern, emerging sequentially to sell purported Gilead HIV medication to the Distributor Defendants in a compressed time period, at prices that were conspicuously inconsistent with legitimate Gilead products.
- 268. The Supplier Defendants also used identical templates for their product lists and DSCSA pedigree documentation. These templates often even share a common typographical error, missing the final "s" in "Gilead Sciences." For example, Defendants Gentek, Omom, PharmaPac, and RXWholesale LLC utilized DSCA pedigree documentation

sharing a common template for DSCSA pedigree document. In addition, multiple of the Supplier Defendants used the same Product List template that appear to have been generated by the same individual. For example, Omom, Invicta, and Rapid's Tex all used the sample product list templates, and the metadata for all three documents indicate that they share a common author.

a. Boulevard's Alter Ego: MFK Management d/b/a Boulevard 9229

269. As alleged above, Boulevard 9229 LLC ("Boulevard") sold thousands of counterfeit Gilead-branded products to Safe Chain, all bearing falsified pedigrees. Gilead now knows that Boulevard's principal-in-fact, Peter Khaim, also controlled newly added Defendant MFK Management, which lists both "Boulevard 9229" and "9229 Boulevard" as assumed names. At Boulevard's request, Safe Chain began sending its payments to Boulevard to bank accounts owned by "MFK Management LLC d/b/a 9229 Boulevard LLC." Safe Chain wired approximately \$10 million to MFK Management as payment for Boulevard's counterfeits.

b. Synergy's Co-Conspirators: Julio Martin Gonzales, Cesar Castillo, and DNS Distributor.

- 270. As alleged above, Defendants Synergy and Carlos Vega sold thousands of counterfeit Gilead-branded products to Safe Chain, all bearing falsified pedigrees. Vega has asserted that Synergy purchased the counterfeits from two recently formed shell corporations: Defendants Cesar Castillo and DNS Distributor. Synergy's bank records confirm that Synergy paid those two entities most of the proceeds of its counterfeiting. However, bank records show that Cesar Castillo and DNS Distributor immediately used that money to purchase jewelry and other expensive goods that can be converted to cash. Cesar Castillo and DNS Distributor are shell entities used to launder the proceeds of Synergy's counterfeiting.
- 271. As alleged above, Defendant Cesar Castillo is a recently-formed Colorado shell company, so-named to intentionally defraud customers into believing that Synergy sourced

its counterfeits from the "real" Cesar Castillo, a Gilead-authorized distributor in Puerto Rico. Vega controls Defendants Cesar Castillo and DNS Distributor.

272. Defendant Julio Martin Gonzalez is the named principal of Cesar Castillo and DNS Distributor. Vega has stated that Martin Gonzalez is actively involved in Synergy's business. Taking Vega at his word, Martin Gonzalez therefore knowingly participated and conspired to participate in Synergy's counterfeit trafficking operation.

c. Gentek and Its Principal, Edel Reyes

- 273. Gentek is a fly-by-night counterfeiter that worked with the Leader Defendants to sell counterfeits to multiple Distributor Defendants. As alleged above, Gentek sold thousands of bottles of purported Gilead medication to Safe Chain. Some of Gentek's counterfeits had Seroquel XL, the powerful antipsychotic, inside the sealed bottle instead of Gilead medication. Gilead has confirmed that all of Gentek's pedigrees for purported Gilead product are fraudulent.
- 274. Gentek is owned by Defendant Edel Reyes, who registered the company at his home address. Gentek opened its doors just months before it started selling counterfeits to Safe Chain, and abandoned its offices before Gilead's investigators visited them. Seized documents show that Reyes actively marketed and sold counterfeits through Gentek.

d. Rapid's Tex and Its Principal, John Santos

- 275. Rapid's Tex is a fly-by-night counterfeiter that worked with the Leader Defendants to sell counterfeits to multiple Distributor Defendants. As alleged above, Rapid's Tex sold thousands of bottles of purported Gilead medication to Safe Chain. Gilead has confirmed that every pedigree for every Gilead product sold by Rapid's Tex is fraudulent.
- 276. Rapid's Tex is owned and operated by Defendant John Santos. It is licensed only in its home state of Texas and therefore cannot lawfully sell across state lines. To

sell to Safe Chain, Rapid's Tex participated in a "pass-through" scam whereby it fulfilled Safe Chain's orders by selling the counterfeits on paper to a different, licensed distributor, which then immediately sold them to Safe Chain.

- 277. Safe Chain itself declared in writing that multiple bottles of Gilead medication sold by Rapid's Tex were "bad/counterfeit," noting that they had "experienced them [i.e., the counterfeits] with another" distributor, and so Safe Chain "could not receive/take" those bottles. Santos, Rapid's Tex's owner, was copied on that email. His response to being told that he had sold counterfeit HIV medication was merely to say "we will be shipping out today another order."
 - e. Omom and Its Principals, Gustavo Fernandez, Luis D. Gonzales Herrero, and Jordan Rodriguez Mato
- Distributor Defendants was orchestrated by the Leader Defendants. Gilead received and tested a counterfeit bottle of BIKTARVY® that Omom had sold to ProPharma, which sold it to a pharmacy. That counterfeit bottle had the wrong pills inside, and a patient reported being sickened by the counterfeit medication. Gilead now knows that Omom sold a total of over 18,000 bottles of purported Gilead medication to both ProPharma and Safe Chain, valued at over \$52 million. Gilead has confirmed every Omom pedigree for these purported Gilead medications to be fraudulent. Omom abandoned its offices after learning that Gilead was pursuing the sellers of counterfeits.
- 279. Omom's principals used fake names to sell counterfeits. In its corporate filings, Omom lists as its principals Defendants Gustavo Fernandez, Luis D. Herrero-Gonzales, and Jordan Rodriguez Mato. As discovery will confirm, these Defendants knowingly participated in Omom's counterfeiting activities.

f. Invicta and Its Principal, Jorge Caba

- Defendants that the Leader Defendants used to sell to ProPharma purported Gilead medication with fraudulent pedigrees. From late May 2021 to the date of Gilead's seizure against ProPharma in August, Invicta sold 3,987 bottles of Gilead medication worth approximately \$11.8 million. Gilead has confirmed that the pedigrees for every bottle sold by Invicta are fake: those pedigrees all claim that Invicta purchased from Smith Drug Company, a Gilead-authorized distributor, which has never sold anything to Invicta.
- 281. As with the other counterfeit suppliers, ProPharma's relationship with Invicta was managed by the Leader Defendants, with sales arranged by the Marketer Defendants. Safe Chain also took steps to add Invicta as a supplier in June 2021, but appears not to have completed that process before this Court enjoined Safe Chain from selling Gilead products.

g. Pharma Pac and Its Principal, Jorge Caba

- 282. Newly added defendant Pharma Pac is the final counterfeit distributor that the Leader Defendants introduced to ProPharma. ProPharma began purchasing purported Gilead medication from Pharma Pac on August 4, 2021, just weeks before Gilead executed the seizure at ProPharma's offices on August 23. During that short period, Pharma Pac sold over 1,000 bottles of purported Gilead medication to ProPharma, valued at over \$3 million. Gilead has confirmed that every pedigree for every purported bottle of Gilead product sold by Pharma Pac is fraudulent they all list a purported first sale from Gilead to an authorized distributor, but Gilead never made those sales to that authorized distributor.
- 283. Pharma Pac's relationship with ProPharma was managed primarily by Leader Defendant Mannava, using his "Srini K" persona. For example, Srini K. sent ProPharma

a "new account application" to set up Pharma Pac as a vendor and supplied ProPharma with a Pharma Pac invoice for purported Gilead medication.

284. Pharma Pac is a fly-by-night counterfeiter that has stolen the identity of an established pharmaceutical repackaging company. There is a legitimate business named Pharma Pac, a licensed pharmaceutical repackaging company, which was founded in 1984. The "Pharma Pac" that sold counterfeits to ProPharma was founded in January 2021, by its owner and principal, Defendant Angel Toral. As part of its attempts to pass itself off as its legitimate namesake, Defendant Pharma Pac fraudulently utilizes the legitimate Pharma Pac's business address on its corporate filings, and even copied the legitimate Pharma Pac's logo on its pedigrees and invoices.

h. RxWholesale and Its Principal Gabriel Betesh

285. RxWholesale is a fly-by-night pharmaceutical distributor that was founded in February 2021, and which received a New Jersey wholesale drug license in late March 2021. RxWholesale lists a business address in Brick, New Jersey – but in a familiar pattern, that office was abandoned by the time Gilead's investigators visited it.

RxWholesale is selling purported Gilead medication with fake pedigrees. For example,
AmerisourceBergen ("ABC"), a Gilead-authorized distributor, provided Gilead a copy of a
confirmed fake pedigree that falsely claimed RxWholesale had purchased BIKTARVY® from
ABC and sold it to Distributor Defendant Scripts. Separately, in June 2021 a pharmacy that was
directly solicited by RxWholesale asked to see the pedigrees in advance, saw that the pedigrees
(falsely) listed ABC as the source of over 500 bottles of Gilead-branded medicines, and shared
that pedigree with Gilead's counsel. And Gilead seized from Safe Chain a copy of
RxWholesale's application to become a Safe Chain vendor, completed just before the seizure

was executed in July 2021. RxWholesale provided a sample pedigree with its application that once again falsely listed ABC as its source, and which listed the wrong address for Gilead as the manufacturer. Defendant Betesh signed the application form as RxWholesale's President.

287. In an unrelated lawsuit filed in New York Supreme Court, a creditor with a security interest in RxWholesale's inventory has alleged that RxWholesale and Scripts conspired to hide millions of dollars' worth of BIKTARVY®, out of state and out of the reach of the New York City Marshal. The creditor attached to its Complaint a copy of an invoice showing that in July 2021 alone, RxWholesale sold nearly a thousand bottles of purported Gilead products to Scripts, all at too-good-to-be-true prices.

i. CM Pharma and Its Principals, Robert and Jeffrey Gafna

288. CM Pharma is an Alabama drug distribution company owned and operated by Defendants Robert and Jeffrey Gafna. CM Pharma is licensed to distribute pharmaceuticals only in Alabama, making it unlawful for CM Pharma to ship across state lines.

289. In April 2021, CM Pharma sold 100 bottles of purported BIKTARVY® to Safe Chain. Safe Chain complained that CM Pharma failed to provide pedigrees for the BIKTARVY®, noting, "The man I spoke with Jeff [Gafna] kind of gave me some run around like answer about why we haven't received them... seemed really odd." On April 16, 2021, CM Pharma finally sent Safe Chain pedigrees that all claimed that Gilead sold the product directly to Invicta, one of the fly-by-night Supplier Defendants, which then sold the product to CM Pharma. Those pedigrees are fraudulent: Gilead never sold any products to Invicta.

4. The Asset Holder Defendants: Co-Conspirators Who Received Payments For The Counterfeits

290. The Leader Defendants and the Supplier Defendants acting in concert with them used a series of closely controlled shell entities to conceal and launder the proceeds of their

sales of counterfeits, and/or to convert these proceeds into cash as payment to the source of the counterfeits. These entities, referred to as the "Asset Holder Defendants," are described below.

a. JM Smith

- 291. Defendant JM Smith is a shell company registered in New Jersey, with Defendant Carlos Hernandez listed as its owner and principal. JM Smith was founded in May 2021, around the same time that the fly-by-night Supplier Defendant Invicta started selling counterfeit Gilead medication to ProPharma. In June and July 2021, Invicta routinely wired the profits of its counterfeiting to JM Smith in several transactions ranging between \$100,000 to \$400,000, totaling approximately \$1.3 million. As alleged above, Invicta is part of the counterfeiting ring organized by the Leader Defendants.
- Leader Defendants, JM Smith is an illegitimate shell company blatantly attempting to steal the identity of a real authorized distributor. One of Gilead's seventeen authorized distributors for its HIV medications is Smith Drug Company, which is a subsidiary of JM Smith Corp., a privately held South Carolina corporation that has been in business since the 1920s. The New Jersey shell company, Defendant JM Smith Distributor Corp., has no connection with the real JM Smith Corp. Rather, the shell company is intended to give the appearance of legitimacy to Invicta's counterfeits, which were accompanied by fraudulent pedigrees claiming that the medications came from Smith Drug Company. Indeed, one ProPharma customer insisted on returning purported Gilead medication after calling the real JM Smith to verify one of those fraudulent pedigrees, which confirmed that JM Smith was not "a part of the supply chain as documented on the pedigree received."

- b. Titan, Tidy Garages, and Their Principal, Gabriel Delgado Ramirez
- 293. Defendants Titan and Tidy Garages are two Florida limited-liability corporations with no pharmaceutical licensure and no known or apparent connections to the pharmaceutical industry. Titan was founded by Defendant Gabriel Delgado Ramirez on August 31, 2020. A few days later, Ramirez filed for reinstatement of Tidy Garages, which had been founded years earlier by a third party and had gone inactive. When he reinstated Tidy Garages, Ramirez listed himself as the new agent and manager.
- 294. On June 21, 2021, Ramirez opened a Chase bank account for Titan. Over the ensuing five weeks, the counterfeit Supplier Defendant Omom deposited over \$2 million into Titan Distribution's newly opened account in several installments. As alleged above, Omom is part of the counterfeiting ring organized by the Leader Defendants. Those deposits from Omom constituted the vast majority of Titan's receipts during that period. In that same time period, Omom also deposited \$62,845.50 to Tidy Garages in multiple transactions. Each deposit from Omom to Titan and Tidy Garages referenced an invoice number.
- 295. In total, from June 21 to July 30, 2021, Omom deposited \$2.19 million into the Titan and Tidy Garages accounts. During that same period, Omom received approximately \$3 million in payments for the counterfeits it sold to Safe Chain. The money deposited with Titan and Tidy Garages thus represents the great majority of Omom's counterfeiting revenues during that time period.
- 296. Omom's only business is selling counterfeits, and Titan appears to have opened its bank account for the express purpose of receiving millions of dollars from Omom. Titan, Tidy Garages, and Ramirez are part of the counterfeiting conspiracy. As discovery will confirm, they are either receiving payment for the counterfeits Omom sold, or are helping disguise and distribute Omom's revenues to the party that is receiving the ultimate payment.

- c. Silverline Pharma, ASB Wholesale, and Their Principal, Alberto Alonso Diaz
- 297. Defendants Silverline Pharma and ASB Wholesale are both Florida limited-liability corporations founded by Defendant Alberto Alonso Diaz on the same day, March 12, 2021.
- 298. As alleged above, Defendant Titan received approximately \$2 million from the fly-by-night counterfeiter Omom. Shortly thereafter, Titan wrote two checks: one to Defendant ASB Wholesale for \$287,053, and another to Silverline Pharma for \$212,297. Both payments referenced an invoice number in the memo line.
- 299. Just as the evidence shows that Titan received proceeds of Omom's counterfeiting as payment for, or to facilitate payment for, Omom's purchase of the counterfeits, Titan's immediate payment of those counterfeiting proceeds to Silverline Pharma and ASB Wholesale evidences that they, too, are co-conspirators which are either receiving or distributing payment for the counterfeits.

d. Make It Happen Marketing and Its Principal, Quan Hernandez

June 22, 2016 by Defendant Quan Hernandez. Make It Happen Marketing's corporate filings list no principal place of business or any corporate officers, and the company has been past due to file its corporate statement with New York State since at least June 2018. Despite its apparent inactivity, between February 18 and March 30, 2021, Make It Happen Marketing received a series of sixteen checks for tens of thousands of dollars each from Boulevard Defendant MFK Marketing d/b/a Boulevard 9229, totaling over \$1.1 million during the six-week span. During that same period, Boulevard was receiving millions of dollars of payments from Safe Chain, into

the same MFK Marketing d/b/a Boulevard 9229 account, for its sale of counterfeit Gilead HIV medication.

- 301. An attorney named Rina Esterov filed Make it Happen Marketing's certificate of incorporation, and the same attorney also filed the certificate of incorporation for Instacare Pharmacy, an entity that appears in the falsified Boulevard 9229 pedigrees as an intermediary distributor of the counterfeits.
- 302. Boulevard is a fly-by-night counterfeiter with no business other than the selling of counterfeit medications. Boulevard's transferring over a million dollars' worth of its counterfeiting proceeds to Make It Happen Marketing indicates that the latter is part of the counterfeiting enterprise, and either received payment for supplying the counterfeits, or is helping disguise and distribute Boulevard's revenues to the party which is receiving the ultimate payment.
 - 5. The New Distributor Defendants: Scripts, USDV Pharma, And Their Principals
 - a. Scripts and Its Principal, Steven Diamantstein
- 303. Defendant Scripts is a pharmaceutical distributor located in Brooklyn, owned and operated by Defendant Steven Diamantstein. Like Distributor Defendants Safe Chain and ProPharma, Scripts is a properly licensed distributor that operates in the gray market, selling discounted prescription drugs outside of authorized distribution channels. And like the other Distributor Defendants, Scripts conspired with the Leader Defendants to willfully sell counterfeit Gilead HIV medication to United States pharmacies.
- 304. In January 2020 and again in March 2021, Gilead learned of complaints that Scripts had sold counterfeit Gilead medication to a pharmacy, which subsequently dispensed it to a patient. Both of those counterfeit bottles of Gilead medication contained antipsychotic

medication: one had high-dose Seroquel XL, and another had generic aripiprazole, another antipsychotic medicine in the same class as Seroquel. And both counterfeit bottles showed signs of tampering. In April 2021, Gilead engaged in a series of correspondence and meetings with Scripts' counsel about its sale of counterfeit Gilead medication. Scripts refused to provide the documents and information Gilead requested about the counterfeits, although it did say it would stop purchasing from Supplier Defendant Gentek, which sold Scripts the counterfeits.

305. In late July 2021, Gilead separately received a communication from ABC, one of its authorized distributors, forwarding a fraudulent pedigree for Gilead medication that Scripts had sent to a pharmacy in Texas. The pedigree claimed that Gilead had sold the bottles of BIKTARVY® to ABC, which had sold them to Defendant RxWholesale, which had sold them to Scripts. ABC confirmed that the purported sale from ABC to RxWholesale was false and never occurred.

306. From information collected at the seizures, Gilead now knows that Scripts is a co-conspirator in the counterfeiting ring, and worked with the Leader and Marketer Defendants to sell large quantities of counterfeit Gilead HIV medication from numerous illicit suppliers, not only Gentek. As alleged above, the Leader Defendants told ProPharma in March 2021 that they were selling "\$8M a week" in HIV medication through Scripts. Potter Decl. 172. Gilead has also received copies of advertising emails that the Marketer Defendants' sales force sent out on Scripts' behalf. In one instance, a pharmacy responded to a sales pitch the Marketer Defendants made on behalf of ProPharma by writing, "what happened to Scripts Wholesale?"

b. USDV Pharma and Its Principal, Jeff Beetley

307. USDV Pharma is a pharmaceutical wholesaler that was founded in April 2021 and received its New York drug wholesaler license on August 7, 2021. USDV Pharma was incorporated by Defendant Steven Diamantstein, the owner of Defendant Scripts, and it is

located in the same building as Scripts: Scripts occupies the third floor of the building, and USDV occupies the second floor. The Diamanstein family owns the entire building.

- 308. On LinkedIn, Defendant Jeff Beetley holds himself out as the CEO of USDV Pharma. Beetley is also a Scripts employee whose job duties included selling Scripts' purported Gilead HIV mediation. For example, when ABC provided Gilead a copy of Scripts' fake pedigree in late July 2021, it provided the corresponding invoice that listed Beetley as the Scripts employee responsible for the sale.
- 309. USDV Pharma (1) has the same owner as Scripts; (2) is located directly downstairs from Scripts in the same family-owned building; (3) employs as its CEO a Scripts employee who recently sold purported Gilead medication with fake pedigrees; and (4) was founded just as Scripts' sale of counterfeit Gilead medication was taking off. As discovery will confirm, USDV Pharma is involved in Scripts' counterfeiting operation.

6. Medicine Shoppe, PrimeRX, and Their Principal, Sekar Venkatesh

- a. Medicine Shoppe
- 310. Defendant Medicine Shoppe *i.e.*, Maryland Pharmacies Inc. d/b/a Medicine Shoppe 1802 is a single franchisee of a national pharmacy chain, owned and operated by Defendant Sekar Venkatesh. It is a modestly sized retail pharmacy in a strip mall in suburban Silver Spring, Maryland. As alleged above, Gilead tested and confirmed to be counterfeit two bottles of Gilead medications that the Medicine Shoppe had purchased from Safe Chain and then dispensed to patients one in October 2020, one in February 2021.
- 311. At the time of these incidents, Gilead treated Medicine Shoppe as a victim. Recently discovered evidence shows that the opposite is true: Medicine Shoppe is a willful large-scale counterfeiter. Despite having twice been informed it purchased from Safe Chain dangerous counterfeit HIV medication including a bottle that contained high-dose Seroquel, the potent

antipsychotic – Medicine Shoppe continued making massive purchases of purported Gilead HIV medication from Safe Chain.

- 312. In total, Medicine Shoppe purchased over 1,300 bottles of purported Gilead medication from Safe Chain, paying Safe Chain \$3.8 million. All of those bottles had fake pedigrees, and Medicine Shoppe purchased the vast majority of them after it knew Safe Chain was selling counterfeit Gilead HIV medication with foreign medication inside. The Medicine Shoppe continued buying large volumes of counterfeit Gilead medication from Safe Chain until Gilead executed the July 23, 2021 seizure at Safe Chain's premises.
- 313. Losing Safe Chain as a supplier did not stop Medicine Shoppe's attempts to buy counterfeits: it simply went straight to Safe Chain's counterfeit suppliers. When Gilead executed the second round of seizures on August 26, 2021, its investigators seized a cell phone from Defendant Peter Khaim, the New York-based principal of the counterfeit supplier Boulevard. On Khaim's phone was a text chain with Defendant Venkatesh, Medicine Shoppe's owner, directly negotiating the purchase of very large quantities of purported Gilead medications:

Triumeq 75 1800 Tivicay. 75. 900 Dyscovy. 300 600 Biktarvy 200. 1800 Truvada 50. 500

(646) 247-1380 Peter Khaim 8/12/2021 2:33:39 PM

Descovy agreed

(410) 908-2814 Sekar 8/12/2021 2:38:00 PM

Triumeq 75 1000 Tivicay 75 600 Biktarvy 200 1200 Thanks

(410) 908-2814 Sekar 8/12/2021 2:40:29 PM

314. This text chain lists the medication, the number of bottles, and the proposed price: for example, Khaim offers BIKTARVY®, 200 bottles, for \$1800 each – a

discount of approximately 45% off WAC – and Venkatesh pushes for a substantially lower price of \$1200. At these prices and quantities, Venkatesh clearly knew the prescription medication he was haggling over was not authentic, lawfully acquired Gilead medication.

315. The sheer volume of Medicine Shoppe's purchases from Safe Chain, and the similarly huge quantities Venkatesh was seeking to purchase directly from Khaim, indicate that not all of these counterfeits were being dispensed to patients through the Medicine Shoppe. Rather, as discovery will confirm, Venkatesh was selling most of his stock of counterfeit Gilead medication through his pharmaceutical distribution company, PrimeRx.

b. PrimeRx

- 316. As Gilead has learned, Venkatesh owns not just Defendant Medicine Shoppe, but also a pharmaceutical distribution company, Defendant PrimeRx. PrimeRx is registered as a pharmaceutical wholesaler with the FDA and holds licenses in a handful of states, including New York. PrimeRx lists its business address as the exact same address and suite number in Silver Springs, Maryland as Defendant Medicine Shoppe.
- 317. PrimeRx has done business with Defendant ProPharma. In March 2021, PrimeRx filled out onboarding paperwork with ProPharma that stated it was a "secondary wholesale drug distributor" and listed its ProPharma "rep" as "Drew" *i.e.*, Leader Defendant Dhruv Ralhan. Although it listed itself as a wholesaler, PrimeRx does not appear to have made any sales to ProPharma rather, PrimeRx used ProPharma to purchase even more counterfeit Gilead HIV medication. PrimeRx purchased hundreds of bottles of purported Gilead medication from ProPharma, all with fake pedigrees. In making those counterfeit purchases from ProPharma, PrimeRx worked directly with Leader Defendant Mannava. As discovery will confirm, PrimeRx subsequently re-sold those counterfeits, as well as additional counterfeits it received from Medicine Shoppe, to pharmacies throughout the United States.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF FEDERAL TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1)(A)) (Against all Defendants except the Relief Defendants)

- 318. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.
- 319. In violation of 15 U.S.C. § 1114(1)(a), Defendants, independently and in conspiracy with one another, used in commerce, without Gilead's consent, either a reproduction, counterfeit, copy or colorable imitation of the Gilead Marks and the Gilead Trade Dress in connection with the sale, offering for sale, distribution, or advertising of counterfeit Gilead products; in connection with the sale, offering for sale, distribution, or advertising of Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States and that are not subject to and subvert Gilead's quality-control measures; and in connection with which such use that is likely to cause confusion, or to cause mistake, or to deceive.
- 320. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.
- 321. Defendants are directly, contributorily, and vicariously liable for their infringement.
- 322. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.

- 323. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.
- 324. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

SECOND CLAIM FOR RELIEF FEDERAL TRADEMARK INFRINGEMENT (15 U.S.C. § 1114(1)(B)) (Against all Defendants except the Relief Defendants)

- 325. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.
- 326. In violation of 15 U.S.C. § 1114(1)(b), Defendants, independently and in conspiracy with one another, reproduced, counterfeited, copied, or colorably imitated the registered Gilead Marks and Trade Dress belonging to Gilead and applied such reproduction, counterfeit, copy or colorable imitation to labels, signs, prints, packages, wrappers, receptacles, or advertisements intended to be used in commerce upon or in connection with the offering for sale, distribution or advertising of counterfeit Gilead products; in connection with the sale, offering for sale, distribution, or advertising of Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States and that are not subject to and subvert Gilead's quality-control measures; and in connection with such use that is likely to cause confusion, to cause mistake, or to deceive.
- 327. For example, and without limitation, the Defendants used counterfeit, reproduced, copied, or colorably imitated Gilead Marks on the labels of the counterfeit bottles of

Gilead HIV medications they purchased, advertised, and sold, as well as on altered and/or falsified pedigrees for bottles of Gilead HIV medications.

- 328. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.
- 329. Defendants are directly, contributorily, and vicariously liable for their infringement.
- 330. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.
- 331. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.
- 332. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

THIRD CLAIM FOR RELIEF FALSE DESCRIPTION AND DESIGNATION OF ORIGIN IN COMMERCE (Against all Defendants except the Relief Defendants)

- 333. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.
- 334. In violation of 15 U.S.C. § 1125(a)(1)(A), Defendants, independently and in conspiracy with one another, in connection with the counterfeit Gilead medication, and in connection with Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States,

and/or that are not subject to and subvert Gilead's quality-control measures, used in commerce a slogan, trade dress, word, term, name, symbol, or device, or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which was or is likely to cause confusion or to cause mistake, or to deceive as to an affiliation, connection, or association with Gilead.

- 335. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.
- 336. Defendants are directly, contributorily, and vicariously liable for their infringement.
- 337. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.
- 338. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.
- 339. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

FOURTH CLAIM FOR RELIEF FEDERAL FALSE ADVERTISING (Against all Defendants except the Relief Defendants)

340. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.

- 341. In violation of 15 U.S.C. § 1125(a)(1)(B), Defendants, independently and in conspiracy with one another, in connection with the sale of counterfeit Gilead medication, and in connection with the sale of Gilead products with altered and/or falsified pedigrees that are materially different from authentic Gilead products authorized for sale by Gilead in the United States and that are not subject to and subvert Gilead's quality-control measures, used a slogan, trade dress, word, term, name, symbol, or device, or any combination thereof, or a false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, and qualities of the counterfeit Gilead medication.
- 342. Defendants advertised, marketed, and promoted the counterfeit Gilead products, and the materially different Gilead products with altered and/or falsified pedigrees, to the public, and/or to specific segments of the public, using the Gilead Marks and Trade Dress, as well as other intellectual property belonging to Gilead.
- 343. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.
- 344. Defendants are directly, contributorily, and vicariously liable for their infringement.
- 345. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.
- 346. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

347. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

FIFTH CLAIM FOR RELIEF FEDERAL DILUTION OF MARK (Against all Defendants except the Relief Defendants)

- 348. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.
- 349. The Gilead Marks and Trade Dress are famous and distinctive within the meaning of 15 U.S.C. § 1125(c).
- 350. Defendants are selling and/or have sold counterfeit, altered, and/or falsified products bearing the Gilead Marks and Trade Dress after such trademarks and trade dress became famous.
- 351. By selling these products, Defendants, independently and in conspiracy with one another, have diluted and are diluting the distinctive quality of a mark or trade name owned by Gilead in violation of 15 U.S.C. § 1125(c).
- 352. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.
- 353. Defendants are directly, contributorily, and vicariously liable for their infringement.
- 354. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.

- 355. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.
- 356. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

SIXTH CLAIM FOR RELIEF NEW YORK DILUTION OF MARK AND INJURY TO BUSINESS REPUTATION (Against all Defendants except the Relief Defendants)

- 357. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.
- 358. All of the Gilead Marks and Trade Dress are individually distinctive under New York General Business Law § 360-1.
- 359. By selling counterfeit, altered, and/or falsified products bearing the Gilead Marks and Trade Dress, Defendants, independently and in conspiracy with one another, have injured and are continuing to injure Gilead's business reputation and/or have diluted and are continuing to dilute the distinctive quality of a mark or trade name owned by Gilead, in violation of New York General Business Law § 360-1.
- 360. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.
- 361. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

362. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

SEVENTH CLAIM FOR RELIEF NEW YORK DECEPTIVE BUSINESS PRACTICES (Against all Defendants except the Relief Defendants)

- 363. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.
- 364. In violation of New York General Business Law § 349, Defendants, independently and in conspiracy with one another, are selling, offering for sale, and/or distributing counterfeit, altered, and/or falsified products unlawfully bearing the Gilead Marks and Trade Dress.
- 365. As a direct and proximate result of Defendants' deceptive conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.
- 366. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

EIGHTH CLAIM FOR RELIEF <u>COMMON-LAW UNFAIR COMPETITION</u> (Against all Defendants except the Relief Defendants)

367. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.

- 368. In violation of the common law of the State of New York and elsewhere, Defendants, independently and in conspiracy with one another, have unfairly competed with Gilead by selling the counterfeit, altered, and/or falsified products.
- 369. As a direct and proximate result of Defendants' unfair competition, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants' conduct is restrained, Gilead will continue to be irreparably harmed.
- 370. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.
- 371. As a direct and proximate result of Defendants' unfair competition, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

NINTH CLAIM FOR RELIEF <u>COMMON-LAW UNJUST ENRICHMENT</u> (Against all Defendants except the Relief Defendants)

- 372. Gilead realleges and incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein.
- 373. By selling the counterfeit, altered, and/or falsified products bearing Gilead's valuable trademarks independently and in conspiracy with one another, Defendants have been unjustly enriched at Gilead's expense in violation of the common law of New York and elsewhere.
- 374. Under principles of equity, Gilead is entitled to restitution and/or disgorgement of Defendants' ill-gotten gains.

TENTH CLAIM FOR RELIEF VIOLATION OF RICO, 18 U.S.C. § 1962(C)

(Against the Leader Defendants, the Supplier Defendants, the Marketer Defendants, and the Asset Holder Defendants)

- 375. At all relevant times, Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC were "persons" within the meaning of RICO, 18 U.S.C. §§ 1961(3) and 1964(c).
- 376. At all relevant times, the Leader Defendants, the Supplier Defendants, the Marketer Defendants, and the Asset Holder Defendants (as described above and listed in Appendix A) (collectively, the "RICO Defendants") were "persons" within the meaning of RICO, 18 U.S.C. §§ 1961(3) and 1962(c).
- Marketer Defendants, and Asset Holder Defendants are each comprised of natural persons and of corporate entities that they formed to carry out the counterfeiting activities described above.

 These corporate entities (listed in Appendix A) constituted an association-in-fact (the "Counterfeiting Enterprise") for the purpose of obtaining counterfeit Gilead-branded HIV medications; trafficking them to Distributor Defendants and pharmacies; distributing false and counterfeit pedigree documentation with the medications that misrepresented the chain of custody of the medications; and laundering the proceeds of the scheme through difficult-to-trace entities that used the proceeds to purchase gold bullion, expensive jewelry, luxury goods, and other items that could be easily converted to cash. This association-in-fact was a continuing and cohesive unit with specific and assigned responsibilities and constituted an "enterprise" within the meaning of RICO, 18 U.S.C. § 1961(4).
- 378. Each RICO Defendant, by engaging in the acts set forth in above, including those set forth in paragraphs 248-302, participated in the operation and management of

the enterprise. At all relevant times, this enterprise was engaged in, and its activities affected, interstate and foreign commerce, within the meaning of RICO, 18 U.S.C. § 1962(c).

- 379. Each RICO Defendant, by engaging in the acts set forth above, including those set forth in paragraphs 248-302, conducted or participated, directly or indirectly, in the conduct of the enterprise's affairs through a "pattern of racketeering activity" within the meaning of RICO, 18 U.S.C. § 1961(1) and (5), in violation of RICO, 18 U.S.C. § 1962(c).
- 380. The RICO Defendants, on numerous occasions, knowingly trafficked in counterfeit Gilead-branded HIV medication. Each unit of counterfeit medication constituted a separate violation of 18 U.S.C. § 2320(a)(1) and a separate act of racketeering.
- 381. The RICO Defendants, on numerous occasions, knowingly trafficked in Gilead-branded HIV medication bearing counterfeit labels, documentation, and packaging. Each such unit of counterfeit medication constituted a separate violation of 18 U.S.C. § 2320(a)(2) and a separate act of racketeering.
- 382. The RICO Defendants, on numerous occasions, and in furtherance of their scheme to defraud and to obtain money by means of false and fraudulent pretenses, knowingly caused to be sent and delivered across state lines by commercial interstate carrier shipments of Gilead-branded HIV medication accompanied by counterfeit pedigrees that fraudulently misrepresented the chain of custody of the medications. Each such shipment of counterfeit medication, and each transmission of counterfeit pedigrees, constituted a separate violation of 18 U.S.C. § 1341 and a separate act of racketeering.
- 383. The RICO Defendants, on multiple occasions and in furtherance of their scheme to defraud and to obtain money by means of false and fraudulent pretenses, knowingly caused to be transmitted, by means of wire communication in interstate or foreign commerce,

writings, signs, signals, pictures, and sounds, including false and counterfeit pedigrees, in violation of the federal wire fraud statute, 18 U.S.C. § 1343. Each counterfeit pedigree transmitted by wire constituted a separate violation of 18 U.S.C. § 1343 and a separate act of racketeering. The RICO Defendants' use of interstate wire communications to continually upload, transmit, and receive data, information, and communications in furtherance of their counterfeiting business, including text messages, mobile phone calls, and emails, was also integral to the scheme and the operation and maintenance of the enterprise.

- 384. Each RICO Defendant committed and/or aided and abetted the commission of two or more of these racketeering acts in violation of 18 U.S.C. §§ 2, 1341, 1343, and/or 2320. The RICO Defendants' racketeering acts were multiple and repeated, comprising thousands of offenses.
- 385. These multiple racketeering acts were related and constituted a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5). The acts alleged were related to each other by virtue of common participants; common victims (patients that depend on authentic Gilead-branded HIV medication, as well as Gilead itself); a common method of commission; and the common purpose and common result of trafficking counterfeit Gilead HIV medication, and of enriching the RICO Defendants while concealing their unlawful activities.
- 386. Gilead was directly and proximately injured by the RICO Defendants' pattern of racketeering activity because Defendants' trafficking in counterfeit Gilead-branded products displaced the sale of authentic products and caused Gilead to lose profits. Gilead was also was directly and proximately injured by Defendants' pattern of racketeering activity because the sale of counterfeit products bearing Gilead's trademarks and Gilead's name damages Gilead's reputation and goodwill.

- 387. As a result of their misconduct, the RICO Defendants are liable to Gilead for its injuries.
- 388. The full scope of the RICO Defendants' fraudulent enterprise is not known, and the RICO Defendants' demonstrated pattern of deceptiveness indicates they may have perpetuated their scheme through entities as yet unknown.
- 389. Pursuant to 18 U.S.C. § 1964(c), Gilead is entitled to recover threefold its damages plus costs and attorneys' fees.

ELEVENTH CLAIM FOR RELIEF CONSPIRACY TO VIOLATE RICO, 18 U.S.C. § 1962(D)

(Against the Leader Defendants, the Supplier Defendants, the Marketer Defendants, and the Asset Holder Defendants)

- 390. Gilead hereby repeats and re-alleges the allegations in paragraphs 1 through 318 above as if set forth fully herein.
- 391. At all relevant times, Plaintiffs Gilead Sciences, Inc., Gilead Sciences Ireland UC, and Gilead Sciences, LLC were "persons" within the meaning of RICO, 18 U.S.C. §§ 1961(3) and 1964(c).
- 392. At all relevant times, the RICO Defendants, defined in paragraph 376 above, were "persons" within the meaning of RICO, 18 U.S.C. §§ 1961(3) and 1962(c).
- described above, and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through the pattern of racketeering activity described herein, in violation of 18 U.S.C. § 1962(d). Defendants committed and caused to be committed a series of overt acts in furtherance of the conspiracy and to affect the objects thereof, including but not limited to the acts set forth above in paragraphs 248-302.

- 394. The RICO Defendants' conspiracy depended upon, among other things, (a) obtaining counterfeit Gilead-branded HIV medication; (b) selling the counterfeit medication through the Supplier Defendants to the Distributor Defendants; (c) the creation of fraudulent and counterfeit pedigrees to accompany the sale of the counterfeits; (d) operating a sales force consisting of the Marketing Defendants to market and sell counterfeits to pharmacies in the names of the Distributor Defendants; (e) creating fraudulent and misleading entities (such as Cesar Castillo and JM Smith) and making numerous misrepresentations for the purpose of creating a false record of legitimacy; and (f) concealing and laundering the proceeds of the counterfeiting through the Asset Holder Defendants, who funneled these proceeds into products convertible to cash to pay suppliers and enrich the RICO Defendants.
- 395. Gilead was directly and proximately injured by the RICO Defendants' pattern of racketeering activity because Defendants' trafficking in counterfeit Gilead-branded products displaced the sale of authentic products and caused Gilead to lose profits. Gilead was also was directly and proximately injured by Defendants' pattern of racketeering activity because the sale of counterfeit products bearing Gilead's trademarks and Gilead's name damages Gilead's reputation and goodwill.
- 396. As a result of their misconduct, the RICO Defendants are liable to Gilead for its injuries.
- 397. The full scope of the RICO Defendants' fraudulent enterprise is not known, and the RICO Defendants' demonstrated pattern of deceptiveness indicates they may have perpetuated their scheme through entities as yet unknown.
- 398. Pursuant to 18 U.S.C. § 1964(c), Gilead is entitled to recover threefold its damages plus costs and attorneys' fees.

TWELFTH CLAIM FOR RELIEF CONSPIRACY TO VIOLATE LANHAM ACT

(Against the Leader Defendants, the Supplier Defendants, the Marketer Defendants, and the Asset Holder Defendants)

- 399. Gilead hereby repeats and re-alleges the allegations in paragraphs 1 through 318 above as if set forth fully herein.
- 400. Each of the Leader Defendants, the Supplier Defendants, the Marketer Defendants, and the Asset Holder Defendants was associated with the Counterfeiting Enterprise described above, and agreed and conspired to violate the Lanham Act, that is, agreed to conduct and participate, directly and indirectly, in the purchase, sale, offering for sale, distribution, or advertising of counterfeit and/or infringing goods, including goods with fake pedigrees, in violation of 15 U.S.C. § 1114(1)(a), 15 U.S.C. § 1114(1)(b), 15 U.S.C. § 1125(a)(1)(B), and/or 15 U.S.C. § 1125(a)(1)(B). Defendants committed and caused to be committed a series of overt acts in furtherance of the conspiracy and to affect the objects thereof, including but not limited to the acts set forth above in paragraphs 248-302.
- obtaining counterfeit Gilead-branded HIV medication; (b) selling the counterfeit medication through the Supplier Defendants to the Distributor Defendants; (c) the creation of fraudulent and counterfeit pedigrees to accompany the sale of the counterfeits; (d) operating a sales force consisting of the Marketing Defendants to market and sell counterfeits to pharmacies in the names of the Distributor Defendants; (e) creating fraudulent and misleading entities (such as Cesar Castillo and JM Smith) and making numerous misrepresentations for the purpose of creating a false record of legitimacy; and (f) concealing and laundering the proceeds of the counterfeiting through the Asset Holder Defendants, who funneled these proceeds to pay suppliers and enrich the co-conspirator Defendants.

- 402. As a result of their misconduct, the co-conspirator Defendants are liable to Gilead for its injuries.
- 403. The full scope of the Defendants' conspiracy is not known, and the coconspirator Defendants' demonstrated pattern of deceptiveness indicates they may have perpetuated their scheme through entities as yet unknown.
- 404. Defendants' actions constitute willful infringement of Gilead's exclusive rights in the Gilead Marks and Trade Dress.
- 405. Defendants are directly, contributorily, and vicariously liable for their infringement.
- 406. As a direct and proximate result of Defendants' conduct, Gilead has suffered irreparable harm to the valuable Gilead Marks and Trade Dress and their reputation in the industry. Unless Defendants are restrained from further infringement of the Gilead Marks and Trade Dress, Gilead will continue to be irreparably harmed.
- 407. Gilead has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.
- 408. As a direct and proximate result of Defendants' conduct, Gilead has suffered damages to the valuable Gilead Marks and Trade Dress and other damages in an amount to be proved at trial.

THIRTEENTH CLAIM FOR RELIEF <u>UNJUST ENRICHMENT</u> (Against the Relief Defendants)

409. Gilead realleges and incorporates by reference paragraphs 1 through 318 of this Complaint as if fully set forth herein.

- 410. The Relief Defendants received funds, real property and interests in real property of the Defendants, which are the ill-gotten gains, or are traceable to the ill-gotten gains, derived from the Defendants' conduct alleged above, without consideration.
- 411. The Relief Defendants do not have any lawful right, title, or interest in or to the funds, real property and interests in real property of the Defendants, which are the ill-gotten gains, or are traceable to the ill-gotten gains, derived from the Defendants' conduct.
- 412. The Relief Defendants obtained the funds under circumstances in which it is not just, equitable, or conscionable for them to retain the funds, and therefore they have been unjustly enriched.
- 413. Gilead is entitled to an order, pursuant to common law equitable principles, requiring the Relief Defendants to disgorge the funds, real property and interests in real property of the Defendants, which are the ill-gotten gains, or are traceable to the ill-gotten gains, derived from the Defendants' conduct, and in which the Relief Defendants have no lawful right, title or interest.

PRAYER FOR RELIEF

WHEREFORE, Gilead demands judgment against Defendants as follows:

- A. preliminarily and permanently enjoining, each and every one of the Defendants and their subsidiaries, parents, affiliates, agents, servants, employees, members, directors, officers, and attorneys, and those persons in active concert or participation with them:
 - (i) from selling any Gilead medication, whether genuine or counterfeit;
 - (ii) from using any of the Gilead Marks and Trade Dress or any marks confusingly similar thereto in connection with the manufacture,

- sale, offer for sale, distribution, advertisement, or any other use of medication;
- (iii) from using any logo, trade name, or trademark confusingly similar to any of the Gilead Marks and Trade Dress, which may be calculated to falsely represent or which has the effect of falsely representing that the services or products of Defendants or of others are sponsored by, authorized by, or in any way associated with Gilead;
- (iv) from directly, contributorily, and vicariously infringing any of theGilead Marks and Trade Dress;
- (v) from otherwise unfairly competing with Gilead in the manufacture, sale, offering for sale, distribution, advertisement, or any other use of Gilead medications;
- (vi) from falsely representing themselves as being connected with Gilead or sponsored by or associated with Gilead or engaging in any act which is likely to cause the trade, retailers, and/or members of the purchasing public to believe that Defendants, or any of them, are associated with Gilead;
- (vii) from using any reproduction, counterfeit, copy, or colorable imitation of any of the Gilead Marks and Trade Dress in connection with the publicity, promotion, sale, or advertising of medications;

- (viii) from affixing, applying, annexing or using in connection with the sale of any goods, a false description or representation including words or other symbols tending to falsely describe or represent such goods as being authentic Gilead medication and from offering such goods in commerce;
- (ix) from diluting the Gilead Marks and Trade Dress;
- (x) from destroying any records documenting the manufacture, sale, offer for sale, distribution, advertisement, or receipt of any product purporting to be Gilead medication; and
- (xi) from assisting, aiding, or abetting any other person or business entity in engaging in or performing any of the activities referred to in subparagraphs (i) through (x) above; and
- B. ordering that, within fifteen days after the entry and service of a preliminary or permanent injunction, Defendants serve and file a written report under oath setting forth in detail the manner and form in which they have complied with the injunction; and
- C. ordering that all infringing material be turned over, seized, impounded, and/or destroyed; and
- D. awarding to Gilead punitive damages from each Defendant in an amount to be ascertained at trial, but in no event less than \$25 million; and
- E. awarding to Gilead statutory, actual damages, or threefold damages in an amount to be ascertained at trial, and costs and attorney's fees; and

- F. awarding to Gilead an accounting, and an award of: (i) all ill-gotten profits from Defendants' manufacture, sale, and/or distribution of the counterfeit medication; (ii) Gilead's lost profits; and (iii) Gilead's remedial costs; and
 - G. awarding to Gilead pre-judgment and post-judgment interest; and
- H. awarding such other and further relief to Gilead as may be just, proper, and equitable.

Gilead further demands judgment against the Relief Defendants as follows: ordering that the Relief Defendants disgorge funds, assets, or things of value they hold or control, in which they have no legitimate interest, that were derived from monies or assets obtained by Defendants as a result of conduct alleged above, plus prejudgment interest thereon, as well as awarding such other and further relief to Gilead as may be just, proper, and equitable.

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Dated: New York, New York

March 4, 2022

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